

People with type 1 diabetes and Do It Yourself (DIY) technology solutions

ABOUT THIS POSITION STATEMENT

Diabetes Australia believes that people with diabetes should have choice and access to diabetes management solutions that help them manage their diabetes to the best of their ability.

Diabetes Australia understands that there are technologies being used by people with diabetes that are not approved for use by regulatory bodies, such as the Therapeutic Goods Association (TGA).

These technologies are not commercially available and are 'built' by individuals with diabetes for their own use. This position statement is written for people living with diabetes (and families of people living with diabetes) to provide background information on Do It Yourself (DIY) technologies, the potential risks and benefits of using these technologies, and what people should expect from healthcare professionals in supporting their use.

This position statement provides general information. Diabetes Australia is not endorsing or recommending any of the DIY technologies discussed in this position statement.

KEY POINTS

1. There are a growing number of people with diabetes using DIY diabetes technology systems to help manage their type 1 diabetes.
2. Diabetes Australia does not endorse these technologies for people with diabetes; they are not approved technologies and are highly experimental. Any person using a DIY technology solution does so at their own risk.
3. However if a person with type 1 diabetes (or a parent or family member) chooses to build a DIY system, they must continue to receive support and care from their diabetes healthcare professional and the health system.
4. The emergence of DIY diabetes technologies poses concerns for healthcare professionals, including medico-legal risks and issues with registration and practice.

BACKGROUND

In type 1 diabetes, the body stops producing insulin. This is the hormone needed to take glucose (the energy source) from the blood supply into cells and organs throughout the body. Without insulin, blood glucose levels rise to dangerously high levels. With too much insulin, blood glucose levels can go dangerously low.

People with type 1 diabetes work to keep glucose levels in an optimal range to maintain good health. This involves regularly monitoring their own glucose levels, either with a finger prick blood glucose check or a continuous glucose sensor, and adjusting their insulin dose as required.

For people with type 1 diabetes (and parents of children with type 1 diabetes), this is a time-consuming, unrelenting, and sometimes difficult process. It often means waking in the middle of the night to monitor glucose levels and treat accordingly. It's a routine that places a heavy burden on families.

While diabetes device companies have continued to research, innovate and develop new technologies, the pace of development and availability of new and better technology solutions for people with diabetes is slow and frustrating.

One of the major innovations which many people with type 1 diabetes have been hoping for is for the ability of glucose monitors and insulin pumps to 'talk' to each other and automate the process of insulin delivery. This is sometimes referred to as an 'artificial pancreas' or closed loop pump system. This technology continues to be developed, however its commercial availability is limited.

Out of frustration, some people affected by type 1 diabetes have developed their own ways of making the devices connect with each other. These DIY solutions are now being used by many people because 'open source' technology solutions are being made available on the internet by people in the community.



CURRENT TECHNOLOGY

As part of their daily diabetes management, people with type 1 diabetes check their glucose levels regularly and adjust insulin doses accordingly. The different tools and devices available include:

Insulin delivery

Insulin injections - insulin is injected under the skin using a syringe or an insulin pen. 'Smart' insulin pens provide historical information about the timing and quantity of recent doses.

Insulin pumps - an insulin pump delivers insulin through a small cannula inserted under the skin. Pumps allow a more fine-tuned approach to insulin delivery by varying the amount of insulin and the timing of delivery. While using an insulin pump may help keep blood glucose more tightly within a desired range, it can also mean more frequent glucose checks.

Glucose monitoring

Blood glucose monitoring - a 'finger prick' blood sample is taken and checked using a blood glucose meter. This provides a 'snap shot' of the blood glucose level at that moment in time. This is the most common form of glucose monitoring.

Flash glucose monitoring - a small, 14-day sensor is worn on the upper arm and measures glucose levels in the fluid under the skin, not blood. The person scans the sensor with a scanning device (or using an app on a smart phone) to see their glucose levels. The scanning device/phone app shows the current glucose level, uses arrows to show if glucose levels are rising, falling or remaining stable, and can track trends over time.

Continuous glucose monitoring (CGM) - a small, wearable device that measures glucose levels continuously, giving a reading of the person's glucose level every five minutes. It provides information on patterns and trends of glucose levels throughout the day and night. Arrows show whether glucose levels are rising, falling or remaining steady. CGM devices can be programmed to sound or send alarms and warnings if glucose levels are getting too high or too low.

Combinations of insulin delivery and glucose monitoring

In recent years, insulin pumps have been integrated with continuous glucose monitors. This means that CGM data is transmitted to the pump and factored into insulin delivery calculations.

In Australia, the only available combined device is the Medtronic 640G insulin pump and CGM system. This device provides a 'hypo minimiser' which means the device can predict lows and cut off insulin delivery to prevent dangerously low glucose levels.

The next generation of this device - the Medtronic 670G - is currently only available in the USA and has both a 'hypo minimiser' (as above) as well as a 'hyper minimiser'. This means the device can also predict high glucose levels and increase insulin delivery to prevent above target glucose levels. Devices with these capabilities are known as 'hybrid-closed-loop' systems.

'Closed loop' technology means that insulin delivery is fully automated; that is, the data from the sensor determines the amount of insulin delivered by the insulin pump without any need for the user to press buttons.

At present, there is no approved product that is a fully closed-loop system. The Medtronic 670G product is 'hybrid closed loop' system because it automates all 'background' or basal insulin, however the user still needs to press buttons to 'dial up' or bolus insulin when they consume carbohydrates.

LIMITATIONS OF CURRENT TECHNOLOGY

While there is a lot of beneficial diabetes management technology available in Australia, there are limitations.

Affordability - Some currently available and approved technologies are expensive and are simply unaffordable for many people with diabetes. Insulin pumps are often covered by private health insurance but there are pressures on the private health system, and some funds are reducing availability of pumps on some tables.

The Australian Government funds an Insulin Pump Program that subsidises insulin pumps for a limited number of children and adolescents under the age of 18 years.

The Australian Government also subsidises CGM for children and young people with diabetes under 21 years. However, there is currently no subsidy for the CGM component for adults over the age of 21 years. Currently, there is no subsidy for Flash Glucose Monitoring.

Connectivity - The ability for different devices to work together is referred to as 'interoperability'. This also refers to how information can be transferred and shared between devices.

In many cases, diabetes devices are 'proprietary', meaning devices from one manufacturer will only work with, and 'talk to', devices and products from that manufacturer.

Many devices will have functional limitations set by the manufacturer. For instance, they may be technically capable of being operated by a mobile phone, however they are configured in a way that prevents this.

The lack of interoperability means that instead of devices automatically transferring data to each other (which is required to operate a closed-loop system), information must be manually entered by the person with diabetes.

Choice - The lack of interoperability means that the person with diabetes often cannot use their pump of choice with their sensing device of choice.

Customisation - Many devices have 'factory settings' that cannot be overridden and therefore the device cannot be fully customised. Some consumers want the ability to finetune their device to ensure it better suits their own needs (for example- setting a personalised target glucose range or setting specific alerts and alarms).

THE 'DIY MOVEMENT'

Within the diabetes community there has been growing frustration at the slow pace of development and availability of new devices, integration of devices and functional capability. Many people with diabetes have great technology skills and in today's technological world, a group of these people have applied those skills to manage and get the most out of their diabetes technology.

The #WeAreNotWaiting movement is a rapidly growing movement of people with diabetes, working together to adapt and augment current technology.

Some existing devices are technically able to do more than just the basic functions taught to users. This includes the ability to control insulin delivery from a computer or phone and 'close the loop' by connecting the CGM data to determine and automate the insulin delivery.

The idea of 'looping' can be very attractive for people with type 1 diabetes. It can relieve some of the daily burden of diabetes tasks by automating them and help people to make better decisions about treatment. Ultimately, this can help people to improve their diabetes management.

The #WeAreNotWaiting movement freely distributes information and instructions for people to understand how to build their own DIY system. There are several different DIY systems available, with many variations to cater for different devices. These are continually being developed by the community.

They use social media channels to provide support to those interested in building their own DIY solutions, which enable people to adapt and augment devices to better meet their needs.

While the number of people currently DIY looping in Australia is low (estimated at approximately 100 people), the numbers are growing each week.



The #WeAreNotWaiting movement is a rapidly growing movement of people with diabetes, working together to adapt and augment current technology.

EXAMPLES OF DIY DIABETES TECHNOLOGIES

There are several different DIY diabetes technologies, all developed by people with diabetes, or parents of children with diabetes. None of these technologies are approved for use through regulatory bodies such as the Therapeutic Goods Association (in Australia) or the FDA (in the US). These technologies are experimental and used at the risk of the person with diabetes.

Nightscout

Nightscout, (or 'CGM in the Cloud'), was the first open source, DIY project developed. It provides users with real-time, remote access to CGM via a personal, self-built (secure) website. Users can read CGM data via the website as well as on smart phones and smart watch apps.

It was developed by parents of children with type 1 diabetes who wanted to view their child's CGM data remotely (for example while the child was at school), although adults with diabetes also use it.

Nightscout also generates graphs and reports using the data from the individual's Nightscout account.

DIYAPS

'Do It Yourself Artificial Pancreas Systems' (DIYAPS) are open source projects available free of charge to everyone. The systems are 'hybrid closed loop' systems.

There are currently three DIYAPS systems to choose from: OpenAPS, Loop and AndroidAPS. Each of them requires the user to build the software themselves.

- 1. OpenAPS** incorporates an insulin pump, a continuous glucose monitor, a small 'computer' that runs the OpenAPS software to automate the insulin delivery, and a smart phone to monitor/control the system.
- 2. AndroidAPS** runs on an Android smart phone (which usually also hosts the continuous glucose monitor) and communicates with an insulin pump via Bluetooth.
- 3. Loop** runs on an iPhone (which also may act as the receiver for the continuous glucose monitor) and communicates with an insulin pump via a Bluetooth adapted communication device called a 'RileyLink'.



ISSUES WITH DIY TECHNOLOGIES

Any person choosing to use DIY systems does so at their own risk.

The systems are considered experimental. No DIY system has been through any regulatory process and all development (past and ongoing) is conducted by people in the diabetes community.

Australia has robust regulatory process for therapeutic devices through the Therapeutic Goods Administration (TGA) which considers all aspects of products including safety and efficacy as part of its approval process.

As DIY systems have not been assessed by this robust regulatory process, there may be concerns about the safety and reliability of systems. However, it is also important to recognise that these systems have been built by people with diabetes for their personal use (or that of their children). Safety is a major consideration for people building these systems.

It is important to note that there have been no randomised controlled trials of DIY systems demonstrating the efficacy of the devices.

The emergence of DIY systems poses issues for healthcare professionals working with people with type 1 diabetes who are using the technology. This includes concerns that health professionals may face medico-legal risks and issues with registration and practice. As the systems do not have regulatory approval, health professionals cannot recommend the use of DIY systems.

The systems are considered experimental. No DIY system has been through any regulatory process and all development (past and ongoing) is conducted by people in the diabetes community.

The Australian Diabetes Society and the Australian Diabetes Educators Association are currently developing advice for health professionals regarding this issue and Diabetes Australia supports the need for this advice. It is important that we help health professionals work out how to best support people with diabetes, while continuing to operate legally and within professional guidelines.

DIY systems are not for everyone. Building and running a DIY system requires a considerable level of health literacy. While the instructions are 'open source' and available for everyone, individuals must still understand the devices and the algorithm and how it works. DIY systems are not available for purchase – it is up to the individual user to source all of the components required to build a system. They also have to troubleshoot any problems.

DIABETES AUSTRALIA'S POSITION

Diabetes Australia believes that people with diabetes should be able to choose the best management solutions for their diabetes.

Diabetes Australia does not endorse DIY systems for people with diabetes, however the inability of currently approved diabetes management devices to 'talk to' each other is prompting people to use DIY solutions as part of their diabetes management.

With the availability of open source software and instructions for how to build a DIY solution on the internet, people with type 1 diabetes cannot be stopped from accessing this information, and we need to ensure people are informed of the full range of management options for type 1 diabetes, as well as their benefits and risks.

We recognise that health professionals cannot recommend DIY technologies to people with diabetes. Health professional recommendations should be for devices that have been approved through the regulatory process for safety and effectiveness.

However, there will always be some people who accept a level of risk and choose to take the DIY approach. These people should continue to receive support and care from their diabetes healthcare professional and the health system.

It is important that we understand the medico-legal and professional issues so that health professionals can continue to support people with diabetes, whatever their diabetes management decision.

Diabetes Australia supports the development of an industry digital standard that would enable devices from different companies to be integrated and 'talk' to each other.