TYPE 1 DIABETES DIY TECHNOLOGY

JDRF UK POSITION STATEMENT

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JDRF for a number of years has played and continues to play a fundamental role in the research to develop and ensure market access of artificial pancreas systems. The route towards fully automated insulin delivery is a continuum; the ultimate goal being fully automated insulin delivery with no need for carbohydrate counting or bolusing for meals and for these systems to be regulated and available on the NHS.

There are a growing number of people with type 1 diabetes in the United Kingdom using *closed-loop systems based on "do-it-yourself" ("*DIY") technology to help manage their condition. These technologies are not commercially available and are 'built' by individuals with diabetes for their own use. They have not been approved for use by regulatory bodies and people use them at their own risk.

While research into and the development of new technologies for management of type 1 diabetes continues, some people have felt frustrated by what they feel is slow progress, while they wait for the market entrance of commercial hybrid closed-loop systems (also known as artificial pancreas systems or automated insulin delivery systems), which at least partially automate insulin delivery based on glucose readings from continuous glucose monitors (CGMs). These frustrations have led to some people (DIYers) devising ways to make insulin pumps, CGMs, and "homemade" closed-loop algorithms communicate with each other thereby constructing closed-loop DIY systems.

JDRF UK cannot endorse the use of DIY tech systems as these products are not regulated and the use of them may carry risks. The organisation, however, respects the rights of people with type 1 diabetes to choose treatments that best fit their needs and how they manage the condition, including the use of DIY technology.

There have been peer-reviewed presentations and publications on the results of DIY systems that have shown clinical benefit. Additionally, many people using DIY systems have reported benefits in clinically defined outcome measurement of their HbA1c levels, as well as reduction in hypoglycemia and improvements in quality of life.

Estimates suggest more than 100 people in the UK are currently using DIY systems to help manage their type 1 diabetes, but there are no definitive records.

JDRF acknowledges the important role healthcare professionals play in the management of a person's type 1 diabetes - however that person decides to manage their condition, whether via prescribed technology or a DIY solution.

There is a greater need for funded training for healthcare professionals around new technological developments in the management of type 1 diabetes. JDRF also believes

enhanced legal and reputational protection will be important for healthcare professionals in order to continue to care for patients who choose to use DIY systems.

JDRF in the UK is part of the JDRF global network of independent charities working towards the same vision: a world without type 1 diabetes.

Context

The last 15 years have seen accelerated progress in terms of type 1 diabetes technology.

Insulin pumps have been available on the NHS since 2003. Continuous glucose monitoring (CGM) has also been available privately in the UK from that time. Flash glucose monitoring has been available for around four years.

Over the last 15 years, people's ability to connect and learn through global communications has also increased. Global type 1 diabetes-focused communities have sprung up through social media and open source software has been developed and improved by the pooled knowledge of the community that uses it. #WeAreNotWaiting is a hashtag for the diabetes tech DIY community on Twitter.

JDRF has contributed to funding Professor Roman Hovorka's artificial pancreas research at the University of Cambridge since 2006. His research has added significantly to the body of evidence showing why automated insulin delivery is so important. Researchers such as Professor Hovorka are committed to making automated insulin delivery technology available to the wider community. Clinical studies demonstrating safety of all new technologies are a prerequisite for regulatory approval, while clinical studies of efficacy are needed for decisions on their cost effectiveness and adoption.

Artificial pancreas research results have been discussed on social media and the DIY type 1 diabetes technology community has been prompted by those findings to build equipment that is intended to achieve the same results.

The Medicines and Healthcare products Regulations Agency (MHRA) regulates medical devices in the UK. The agency has no jurisdiction over individuals but is obliged to ensure products can only be used as designed by the manufacturer and used within warranty.

In October 2017 JDRF announced its new initiative to encourage manufacturers to make their devices interoperable by using open communication protocols. This simply means that devices can communicate with other devices because they use the same digital language.

Limitations to current technologies

Even though diabetes technology is developing at a rapid pace, there are a number of limitations to what is currently commercially available.

Availability: there continues to be a postcode lottery across the UK for access to the latest technology as decisions around prescribing are made at a local level. Clinical Commissioning Groups hold the budgets locally and determine how and what treatments

and devices are prescribed. There are also some areas where CCGs have exclusive contracts with device manufacturers, further limiting patient choice.

Cost: the price of much of the latest diabetes technology can be prohibitive to many people if they are having to fund privately.

Connectivity: many devices available for the management of type 1 diabetes are 'proprietary,' meaning devices from one manufacturer will only talk to other devices from the same manufacturer, or to devices from another manufacturer under the framework of a business arrangement. This in turn limits patient choice in the different devices they are able to use. Some devices also have limitations on them that stop them being able to communicate with a receiver such as a mobile phone, even though they are technically capable of doing so.

Tech Literacy: the ability to use the latest technology requires education for both patients and healthcare professionals, which is not always readily available.

DIY Community Technology Examples

Each DIY or 'open source' system has the following main components: an insulin pump, CGM, a device to run the algorithm and/or enable communication among the devices, and a cloud storage account. They use various combinations of CGM, pump and Android or Apple technologies.

There are three main systems available to those who choose this method to treat their type 1 diabetes. All systems are unregulated.

1. OpenAPS uses an insulin pump, CGM and a microcomputer to run the algorithm and communicate between the pump and CGM
2. AndroidAPS uses an Android smartphone, an insulin pump and CGM
3. Loop uses an iPhone platform, an insulin pump and CGM

Recently JDRF announced support for the nonprofit company Tidepool to develop Tidepool Loop - with the aim of bringing the app Loop through regulatory processes and allowing for communication with currently available insulin pumps and CGM devices. This effort is aligned with JDRF's Open-Protocol Initiative, launched in 2017 and backed by a $6m funding commitment from Helmsley Charitable Trust and JDRF in 2018.

These systems use apps and websites including:

xDrip+ is an open source app which is downloaded to an Android phone and intercepts the signal of a CGM transmitter so it can be read by a mobile phone and uploaded to the cloud, and makes suggestions about insulin adjustment based on the CGM readings.

Nightscout is a website that uploads CGM data via the cloud so it can be read remotely in real time, for example when a child is at school or away from home, or by the clinic.

Challenges with DIY Technologies

Those choosing to use a DIY tech system do so at their own risk. DIY systems are not currently regulated by any official authority, anywhere in the world, so there is no official mark of approval indicating the system is safe to use. We do recognise that as these systems are built by people for their own use, safety will be at the forefront of their minds however.

There are always risks with using devices that are old or out of warranty and many manufacturers state that using a device in a way other than it is designed to be used will void the warranty.

As stated on page 1 of this briefing, healthcare professionals should be able to support patients no matter what tools they choose to use to manage their condition, without fear of legal action or risk to professional reputation if something goes wrong when a patient chooses to use a DIY system. It is also not as simple as a patient offering to write the healthcare professional a letter to indemnify them, JDRF would like to see clarity on this issue so that health professionals can feel protected in these situations, as well as resources and protected time for professional learning and development, so that they can continue to care for patients who choose to use DIY systems.

There have not yet been any academic publications of prospective clinical studies with DIY systems determining their safety, although observational data is available. Results of such studies will be one of the requirements for regulatory approval of DIY systems just as they would be for any conventionally developed system.