Appearance of Do-It-Yourself closed-loop systems to manage type 1 diabetes

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Key words

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Abstract

Access to proprietary closed-loop insulin pump systems is limited. The use of Do-It-Yourself closed-loop systems in Australia is growing. A 2017 Facebook group survey indicated that 20 individuals were actively looping with another 38 yet to commence despite the lack of regulatory body approval. Improved glycaemic control with less hypoglycaemia and better sleep were the main benefits. Local health professionals need to be aware of this technology.

The management of type 1 diabetes is on the threshold of a major disruption, due to technological advances allowing for automated insulin delivery that mimic pancreatic beta-cell function, by combining insulin pump technology and continuous glucose monitoring (CGM) systems with an algorithm that determines insulin delivery. This describes a fully closed-loop system where minimal intervention is required. Hybrid closed-loop systems manage basal insulin delivery but require ongoing attention by the user for other functions, including dosing for meals, adjustments for exercise and equipment maintenance. Open-loop systems currently available in Australia allow predictive suspension of insulin delivery to avoid hypoglycaemia. The Medtronic MiniMed 670G Hybrid Closed-Loop System was approved by the US Food and Drug Administration (FDA) in September 2016. In June 2018, it received the CE (Conformité Européenne) Mark and FDA approval for use from the age of 7 and above. As a result, more individuals are using such systems but this technology is not currently available for public consumption worldwide, Australia included. The term ‘artificial pancreas’ is sometimes used interchangeably with closed-loop technology but this can be misleading as current systems are neither fully automated nor independent and do not replace the whole pancreas.

In 2013 the moniker #WeAreNotWaiting was created by the DIY community to denote the need for (i) more rapid development of diabetes technology, (ii) more interoperability of systems and (iii) better data exchange. This hashtag has been adopted by the closed-loop community striving to overcome the limited availability and restrictions of proprietary systems. As of 9 July 2018, over 725 individuals worldwide use DIY systems, with the majority in the United States and Europe.

A closed-loop system requires a processor capable of receiving CGM sensor data, and algorithms to control the rate of insulin delivery through a compatible insulin pump. This results in dynamic basal rates in response to changing glucose levels. For the majority, only the older, out of warranty Medtronic pumps have been compatible as the communication protocols are closed in most newer pumps. It is important to note that the pump itself is not altered but is acting on instructions that are sent to it.

The three main DIY loop software systems in use are OpenAPS, Loop and AndroidAPS, all facilitating hybrid closed-loop systems. More information about these systems can be sourced online. None has regulatory body approval as they have not undergone clinical trials mandated for such technology. Despite this, their development and use have increased as the instructions are freely available on the internet. The ability for customisation also underpins their popularity, with more features available than in any current commercial systems. For example, DIY systems allow the glucose target range to be set individually, which is not possible in commercial systems.
to be individualised; this is not available in current commercial systems.

Individuals using DIY systems are colloquially known as Loopers. Loopers report improvement in their quality of life.8 There have been at least 5,400,000 loop-hours of real-world experience using DIY systems. As these systems are non-proprietary and considered experimental, the end user is responsible for building and maintaining the system, being fully aware of the risks involved and the need to rely on the open source community for troubleshooting.

Local interest in DIY systems has increased over the last 10 months, which is measured by the increasing membership of the closed Facebook group9 that supports and facilitates Australian loopers. Members include people with diabetes, carers and healthcare professionals (HCP). The number of active and potential loopers is difficult to estimate as the information to build systems is freely available online without registration. In this study, we aimed to describe the Australian looping community, specifically to understand who they are, their motivations for the DIY approach and the challenges faced by these individuals and their HCP.

In December 2017, an invitation to participate in an online survey was posted to the previously described Facebook group and the survey was open for 2 weeks in total. The survey was anonymous, consisted of 20 questions and on average, took approximately 6 min to complete. Consent to participate in the study was implied by completing the survey. A copy of the survey is detailed in Appendix S1, Supporting Information.

Of the 130 members at that time, 68 individuals responded, 68% of whom were female. The majority were from Victoria (n = 33) and NSW (n = 20), with all states represented except for the Northern Territory. There were 20 loopers, with another 38 individuals interested in looping but had yet to commence. The remaining 10 were either carers for people with diabetes (n = 5), interested in learning (n = 2) or unsure about the technology (n = 3).

Table 1 describes the characteristics of 19 of the 20 loopers (incomplete data in one respondent). Four respondents were carers of loopers (three children and one adult). Of the 19 loopers, 26% (n = 5) were between 30 and 39 years of age. Two individuals were >60 years, two were teenagers and one was <10 years of age. All loopers were on pump therapy prior to looping, with a median duration in the 6–10-year bracket: 42% (n = 8) had been looping for <3 months. Three individuals had been looping for >18 months, with the rest falling between 3 and 18 months. OpenAPS and Loop were the most commonly used systems; 53% discovered looping on the internet and 21% through social media. There were three individuals uncertain about pursuing the DIY approach citing insufficient knowledge (n = 2), lack of technological confidence (n = 1), uncertainty about securing a suitable pump (n = 1), lack of security in receiving support if it became necessary (n = 1) and the cost of CGM (n = 1).

Loopers (n = 19) in this survey describe (i) more time in target glucose range (100%), (ii) better sleep (79%), (iii) less frequent hypoglycaemia (74%), (iv) improved HbA1c (68%), (v) less severe hypoglycaemia (53%), (vi) more confidence (47%), (vii) more energy (37%) and (viii) fewer mood swings (32%). The mean low- and high-glucose targets were 4.4 and 7.6 mmol/L respectively. The comments from loopers (Table 2) provide insight into the perceived benefits of looping. Concerns were raised regarding the ownership of backup systems to loop should the primary system fail (n = 2) and the reliability of the open source software (n = 1). Two individuals had experienced hardware failure resulting in the inability to resume a closed loop for more than 24 h.

Discussion

Previous studies have suggested a reduction in psychosocial burden10 and improved glycaemic control11 with closed-loop systems. Similar benefits have been reported with OpenAPS, initially in 201612 and more recently this year at the 78th scientific sessions of the American Diabetes Association. This presentation by Dana Lewis reported beneficial effects on mean HbA1c and glucose, as well as more time in target glucose range (increased from 75.8% to 82.2%).13 The findings in our study are supportive.

The nature of the DIY approach and the lack of regulatory approval introduce many challenges for the looper and HCP. The typical looper is motivated, and procurement of reliable compatible equipment, and the cost of CGM are the main challenges. Initiative and some technical understanding are also prerequisites. There is an element of risk using unsupported hardware or software and they are reliant on community support should something go wrong. For the HCP, there may be medico-legal implications endorsing the use of ‘non-approved’ technology. Unfamiliarity and a perceived lack of support may also prove detrimental to the looper–doctor relationship.

Although the use of DIY systems locally is in its infancy, many are interested. The Facebook group membership (established August 2017) has risen steadily (130 in December, 210 in January, 311 in March and 446 in August) and DIY use is likely to increase with time, regardless of whether it has received regulatory
Table 1 Individual characteristics of the looping cohort (n = 19)

| No | Gender | Age group | Type | Duration of diabetes (years) | Duration of pump therapy prior to looping | Duration of looping (months) | System | Less frequent hypos | Less severe hypos | More time in target range | Improved HbA1c | More energy | Better sleep | More confidence | Fewer mood swings | Low glucose target (mmol/L) | High glucose target (mmol/L) |
|----|--------|-----------|------|-------------------------------|------------------------------------------|-----------------------------|--------|---------------------|-------------------|-------------------------|----------------|-------------|--------------|----------------|------------------|-----------------------------|-----------------------------|
| 1  | M      | 30–39     | Carer | 21–25                         | <1 year                                  | 7–9                         | AndroidAPS | Yes                 | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 3.9                         | 9.2                         |
| 2  | M      | 50–59     | PWD 41–45 | <1 year | 7–9                         | OpenAPS                 | Yes                 | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 5.2                         | 5.2                         |
| 3  | M      | 30–39     | PWD 16–20 | <1 year | <1                         | Yes              | OpenAPS                 | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.1                         | 6                           |
| 4  | F      | Under 10  | Carer | 0–5                           | <1 year                                  | 1–3                         | Loop                       | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 5.8                         | 8                           |
| 5  | F      | 30–39     | PWD 6–10 | 1–5 years | 10–12                     | Loop                       | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 3.7                         | 6.7                         |
| 6  | M      | 20–29     | PWD 0–5 | 1–5 years | 10–12                     | Loop                       | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 5.9                         | 10                          |
| 7  | F      | 30–39     | PWD 11–15 | 1–5 years | 16–18                     | Loop                       | OpenAPS & AndroidAPS     | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 5.4                         | 5.6                         |
| 8  | M      | 20–29     | PWD 6–10 | 1–5 years | >18                      | OpenAPS & Loop            | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.7                         | 7.5                         |
| 9  | M      | 30–39     | PWD 16–20 | 11–15 years | 1–3                     | Loop                       | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.8                         | 8                           |
| 10 | F      | 60 or older | PWD 31–35 | 11–15 years | <1                     | Loop                       | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.8                         | 8                           |
| 11 | F      | 60 or older | PWD 31–35 | 16–20 years | >18                     | OpenAPS & Loop            | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.5                         | 7                           |
| 12 | M      | 40–49     | PWD 31–35 | 16–20 years | 1–3                     | OpenAPS & Loop            | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.5                         | 7                           |
| 13 | F      | 60 or older | PWD 31–35 | 16–20 years | >18                     | OpenAPS & Loop            | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 7.5                         | 10                          |
| 14 | F      | 40–49     | PWD 16–20 | 16–20 years | No data                   | Loop                       | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.5                         | 7                           |
| 15 | F      | 50–59     | PWD 26–30 | 16–20 years | 1–3                     | Loop                       | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.5                         | 7                           |
| 16 | F      | 30–39     | PWD 31–35 | 6–10 years | 4–6                     | OpenAPS                   | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.5                         | 7                           |
| 17 | F      | 10–19     | Carer 11–15 | 6–10 years | 4–6                     | Loop                       | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.5                         | 10                          |
| 18 | M      | 40–49     | PWD 6–10 | 6–10 years | >18                     | OpenAPS & Loop            | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.5                         | 10                          |
| 19 | F      | 20–29     | PWD 26–30 | 6–10 years | <1 month                  | Loop                       | Yes               | Yes               | Yes               | Yes                     | Yes            | Yes         | Yes          | Yes            | Yes              | 4.5                         | 10                          |

PWD, person with diabetes.
Table 2 Comments from loopers

| Comment                                                                 |
|-------------------------------------------------------------------------|
| “All good, will never go back. Time, time, time. Don’t have to constantly think about T1 management”. |
| “iPhone software updates can cause occasional frustrations”.            |
| “So much of my brain is freed from diabetes management. Less effort and less stress with better results”. |
| “This is life changing stuff that needs lots more support. Hopefully adding to my life expectancy”. |
| “Looping requires commitment to learning how to do it properly and how to give the system good information. Garbage data in = garbage result out. Once established, looping makes life ridiculously easier and so much less time has to be spent on diabetes management”. |
| “More hypos but getting sorted. A lot better control. Only early days”.  |
| “You need to have an amount of intelligence to be able to set it up properly”. |
| “Looping has changed my life. Last A1c pre Loop was 8.0. Best since Looping 5.0. I have had issues with CGM supplies and costs resulting in not looping for several weeks”. |
| “Best thing I ever did. Burden of diabetes significantly less. Everyone should have access to this!” |
| “It has changed my life for the better. I could never have gotten control like this no matter how hard I tried. However it has given me some anxiety e.g. water activity “what will I do without my loop”, constantly checking I have a “green circle” and feeling panicked if I don’t. My husband also calls my Riley link “the other man in our relationship” It also has required me to become more creative with how I wear my pump and the Riley link”.† |

†Riley link: Hardware component of Loop that processes CGM data and sends instructions to the insulin pump. CGM, continuous glucose monitoring.

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approval or not. The latter is possibly the main reason that HCP may not support its use, but ignorance of such technology may also be contributory. Interestingly, data from 19 loopers indicate that 68% (n = 13) had discussed their approach with their endocrinologist, all of who were supportive. Three loopers did not have an endocrinologist and three had yet to discuss it with their endocrinologist. Clinicians’ attitudes can influence the uptake of technology14 and it is hoped that this paper will encourage a better understanding of the DIY movement. Educating HCP in this niche area will require the recruitment of expert educators; this would be the loopers themselves.

These data have limitations by virtue of their methodology and small sample size but qualitatively provides some insight into the DIY community. It is self-reported and relies on the surveyed population’s motivation. Duplicate survey submissions were unlikely as the logged internet protocol address with each submission was unique.

In Australia, it is important to note that the majority of individuals with type 1 diabetes are managed with multiple daily injections and the looping population described is unique. Even for those on pump therapy, many have difficulty with simpler regimens. What is clear is that there is a growing number of individuals willing to manage diabetes differently and it is important that the medical community is made aware of this.
Supporting Information

Additional supporting information may be found in the online version of this article at the publisher’s web-site:

Appendix S1. Survey.