#We are not waiting - DIY APS Do-It-Yourself Artificial Pancreas Systems: The story so far

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Br J Diabetes 2022;**22**(Supp1):S82-S84

Key words: closed-loop, DIY, open-source, technology

Introduction

In 2015 Dana Lewis, a person with diabetes, developed her own hybrid-closed loop system and began the #WeAreNotWaiting movement (Figure 1). These systems, often called "do-it-yourself" artificial pancreas systems (DIY APS) or open-source closed-loop automated insulin delivery systems, combine an insulin pump, a sensor and an algorithm to maintain glucose levels in range. Whilst early versions were "hybrid" – in other words they still required manual bolusing-- the newer versions of the algorithm have been used as a fully-closed loop (no bolus required!) by some individuals. An article written in 2019 provides further detail on these systems and some of the issues associated with them.[1]

These systems filled a gap by circumnavigating the approvals that commercial companies require in order to launch similar systems. There are three systems commonly encountered: OpenAPS, AndroidAPS and Loop.[1] At the time of writing all three systems are unapproved and unregulated. When these systems first entered UK services the evidence was limited. However, self-reported outcomes from users of the systems were encouraging from both glycaemia and safety points of view.[2-4]

At that time, the approach taken across UK diabetes services was inconsistent and guidelines from the General Medical Council and others were unclear.[5] Work was undertaken to explore the opinions of UK healthcare professionals; initial position statements were produced by Diabetes UK and other organisations to support users of these systems.[6,7] We also explored the concerns of individuals with diabetes commencing the use of these systems, and were able to demonstrate that they were less concerned with safety and regulatory issues than healthcare professionals but that they were worried about a negative response from their healthcare teams (Figure 2).[8]

The Association of British Clinical Diabetologists launched an audit in 2019, which I have been pleased to be heavily involved with, and which now contains routine clinical data from more than 100 DIY APS users in the UK.[9] This work was recently reported at the Advanced Technologies and Therapeutics in Diabetes Conference 2022, where we were able to demonstrate that DIY APS are

Figure 1. DIY-APS – the #WeAreNotWaiting movement

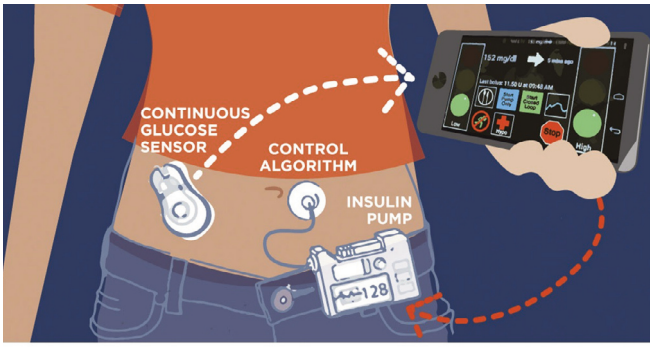

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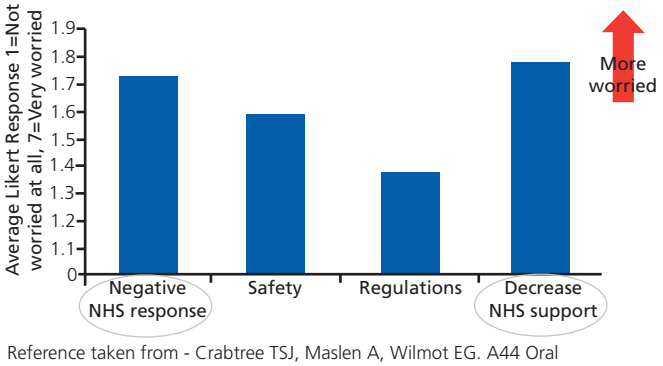
Figure 2. User concerns before commencement



Reference taken from - Crabtree TSJ, Maslen A, Wilmot EG. A44 Oral presentation: initial insights into do-it-yourself artificial pancreas system user expectations and concerns prior to commencement: A pilot questionnaire. DUKPC 2020

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https://doi.org/10.15277/bjd.2022.373

Figure 3. What should our approach be as healthcare professionals?

- We would initiate discussions about DIY APS **but** need to provide full information regarding available options and risks vs benefits
- Checking the basics! (Cannual changes, spare pens)
- We should discuss the risks of DIY APS especially around out-of-warranty equipment if used
- Should continue to support the supply of NHS funded insulin pump, CGM of Flash GM
- Should participate in the ABCD DIY APS audit

associated with improved glycaemia and appear to be safe.[10,11]

In addition to these findings, others have compared DIY APS to commercial systems, often with favourable glucose outcomes (despite often lower HbA_{1c} and higher time-in-range at baseline) and reassuring safety data.[12-14] It is difficult to draw conclusions from observational data but with the systems being actively used in the real world there were limited other means to understand them better in the current cohort of users. That being said, AndroidAPS has recently been put through a randomised controlled trial. The results were recently published in the *New England Journal of Medicine*,[15] and are similar to those seen in the real world.

Whilst glycaemia and safety outcomes are important, the most impressive things often found in users of these systems are the vast improvements in quality of life, sleep and reduced burden of day-to-day diabetes management.[16,17] People come to clinic using these systems and readily report "I don't feel like I have diabetes anymore".

How do we provide practical support to users of these systems? Some of the take- home points are listed in Figure 3. Most people working with diabetes and technology probably feel more comfortable supporting these systems clinically now than they did in the past: the wave of commercial systems and the NHS England pilot project to assess commercially available hybrid closed-loop systems in real clinical use in the NHS have been a crash course in closed-loop insulin management.[18] Other teams have assessed the ethics of the situation,[19] and I was really pleased to see the publication of an international consensus piece on the management of these systems. It is a must-read for anyone who encounters DIY APS users in their clinics.[20]

It will be interesting to see what the future holds. I would encourage anyone seeing users of these systems in clinic to participate in the ABCD DIY APS audit which will continue to undertake surveillance and report outcomes.[9] One thing is for sure: DIY APS seem unlikely to be going anywhere in the short term. They provide an excellent example of citizen science, and the power of the diabetes community advocating for themselves.

Key messages

- Open-source or DIY closed-loop systems were developed by people with diabetes and have been in use since 2015
- These systems are unregulated and unapproved; understanding the ethical situation and management of users of these systems has been complex but we are no supported by robust consensus guidelines
- Data from clinical trials and observational studies suggest that, amongst current users, these systems are likely to be safe and effective

Conflict of interest TC has received personal fees from Abbott Diabetes Care, Lilly, Sanofi, Insulet and NovoNordisk; REJR has received speaker fees, and/or consultancy fees and/or educational sponsorships from BioQuest, GI Dynamics and Novo Nordisk; EW has received personal fees from Abbott, Dexcom, Eli Lilly, Embecta, Insulet, Medtronic, Novo Nordisk, Roche, Sanofi, Ypsomed.

Funding None.

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