Hybrid closed-loop therapy: the calm before the storm

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The upcoming National Institute for Health and Care Excellence (NICE) technology appraisal (TA) for hybrid closed-loop (HCL) therapy is all but finalised and whilst we eagerly await its publication there is a moment to take stock. It's the deep breath before the plunge. I started my registrar training in 2017 and became an Association of British Clinical Diabetologist's (ABCD) research fellow in 2019. My journey has mirrored closely that of access to diabetes technology. I work in Derby, an area of early high uptake of FreeStyle Libre. Then I was involved with do-it-yourself artificial pancreas systems and finally I have been immersed in a world of hybrid-closed loop therapy and the NHS England pilot. Now, nearing the end of my training, I am thinking about what a service needs to do to get this vital technology into the hands of people living with diabetes.

Randomised controlled trials for the systems consistently demonstrate reductions in HbA_{1c} and improvements in time-in-range (3.9-10 mmol/L).[1-3] These improvements are more significant still when the focus shifts to individuals with higher HbA_{1c} levels, as has been borne out by both randomised controlled trial data in ADAPT and real-world data in the ABCD audit of the NHS England pilot.[4,5] Anyone who has spoken to a closed-loop user in clinic will recognise the huge psychological and quality-of-life benefits: this too has been shown in multiple trials.[5,6] We also know from the AiDAPT trial (lots of similar trial acronyms!) that one of the systems has demonstrable efficacy in pregnancy, improving glucose outcomes, which hopefully translates into improved outcomes for both mother and baby.[7]

Technology is not perfect, it would otherwise be indistinguishable from magic. We need to navigate around potential stigma related to wearable technology, especially when this intersects with other characteristics such as ethnicity or gender. There is concern around the potential early worsening of retinopathy. This has not been fully explored, and we are working on a means to understand it, capture the outcomes and develop recommendations to mitigate this risk. We also need to upskill the broader NHS to recognise the technology and to alert the diabetes team when it is present. This is particularly true of inpatient care and the upcoming JBDS guideline will undoubtedly assist; in the meantime the Diabetes Technology Network-UK (DTN) guidelines are a good starting point for stand-alone pump therapy, with principles that can be broadly extended to HCL.[8]

There are probably a few other specific niche questions that might require evidence to answer. I remain curious that the handful of individuals with gastroparesis on HCL that I have looked after seem to have significant improvements in their gastroparesis symptoms on closed-loop therapy. I suspect that this improvement is related to reduced glycaemic variability.

The NICE technology appraisal means we need to get our services into gear to deliver HCL. A technology appraisal is not just a recommendation: it is a legal mandate to provide this technology to people with diabetes. The draft criteria are broad, and it is likely the majority of individuals with type 1 diabetes (T1DM) will meet them.[9] Recognising this, NHS England have asked for the roll-out to occur over a 5-year period rather than the usual three months. This seems sensible as long as inertia within Integrated Care Boards, and financial and staffing pressures within Trusts, do not result in services leaving this to the last minute.

There is also a question around prioritisation. Within any service some individuals may benefit more but advice on this is difficult and may look different from one centre to another. We will need to think smartly about implementation. COVID-19 really forced everyone to dip their toes into a virtual world and using this virtual world to deliver the service is likely to help increase the speed with which we can get this tech into the hands of people with diabetes. We also need to think hard about how we create capacity to deliver this within existing service constraints.

It is becoming clear that all doctors working in diabetes will need to have some working knowledge of technology, rather than just the handful who are in the pump clinic. It may be that a two-tiered approach means those who have difficulties despite the technology are seen in sub-specialty clinics but for the majority who do well a general (or community) diabetes review should suffice. There are some excellent resources. These include:

- Glooko Academy – https://go.glooko.com/academy
- DTN best practice guide[10] – https://onlinelibrary.wiley.com/doi/10.1111/dme.15078
- Panther program tools – https://www.pantherprogram.org/
- DTN-YDEF Tech Course (for SpRs) – https://abcd.care/events/ydef-dtn-uk-technology-course-sprs-dec-2023

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- Leicester Tech Course – https://www.leicesterdiabetes centre. org.uk/practical-diabetes-technology-course

It's certainly an exciting time for the world of T1DM, and I can't wait to be a part of it.

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