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The Artificial Pancreas: Challenges and Opportunities

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After a long lead-in period, the artificial pancreas (AP) is a technology whose time has come. The concept of closed-loop insulin delivery for people with diabetes in response to near-continuous blood glucose monitoring (CGM) was first elaborated in the 1950s, and functioning bedside and wearable systems were subsequently developed in the 1970s and 1980s. However, uptake of these systems was limited by the size and complexity of component devices, and by clinical and technical challenges of various kinds.

More recently, advances in algorithmic design and technological miniaturisation, and the development of accurate and user-friendly CGM sensors, have led to dramatic progress in the development and testing of wearable AP systems. Following successful laboratory studies, recent research has demonstrated the feasibility, safety and efficacy of a wearable AP system in the home setting over a prolonged (12-week) period, with adult participants experiencing an 11% improvement in the time spent in glucose target range and a 39% fall in hypoglycaemia. Commenting on the study, Karen Addington (Chief Executive of JDRF, which part-funded the research) said: ‘These results show that we are thrillingly close to what will be a breakthrough in medical science.’

Despite the impressive clinical outcomes arising from AP usage, it is important to recognise the complexity and unpredictability of user engagements with new medical technologies, since these factors are likely to impact on the long-term usage and success of any given device or system. These considerations are especially pertinent in the AP context, since most systems involve multiple devices – typically, a body-mounted CGM monitor, a platform device (e.g. a smartphone) running a control algorithm, and a body-mounted insulin pump – in addition to placing considerable requirements on users in terms of training, equipment management, and user input (e.g. finger-prick calibrations of CGM sensors and manual input of prandial carbohydrate consumption). These factors are often marginalised in the biomedical literature, as exemplified in a 2011 overview of AP research which devotes only a few short sentences to ‘human factors.’ Yet it is well known that user interactions with technologies can be highly variable, leading to divergent usage and outcomes among different individuals and groups – outcomes that may be further affected by the particularities of users’ interactions with clinical staff and significant others. Consequently, it is imperative to explore the complexity of technological encounters and their relationship with wider, psycho-social issues.

Researchers have recently begun to investigate some of the specific challenges surrounding AP usage. Qualitative research in adolescents highlights concerns about calibration difficulties, frustrations arising from equipment failure, disturbed sleep owing to low blood glucose alarms, discomfort arising from inserting insulin infusion sets, and concerns about wearing and managing multiple devices. More fundamentally, some users were troubled by the need to allow AP systems to ‘control’ their bodies. As demonstrated in a study recently reported in this journal, it is not unusual for a number of potential participants to drop out of AP studies owing to poor acceptance of AP systems, or for other unanticipated ‘deal-breakers’ (as this ongoing qualitative study at Cambridge is exploring); it is also common for users to make partial use of AP systems (i.e. using the system less than 100% of the time, or with ‘open-loop’ functionality only), for reasons still to be fully explored. And, in common with other kinds of medical wearable technologies, AP systems can present challenges if users feel that they act as reminders of their illness, or broadcast its presence to others. Consequently, AP usage presents a host of complexities and challenges that are little understood at present. In this context, Professor Helen Murphy of UEA (the University of East Anglia) noted in 2013 of CGM sensors in particular, 'At this point in time we have the technology, but we don't have all the answers.'

Users' complex encounters with AP systems generate opportunities as well as challenges, with research attesting to a number of positive psychosocial outcomes including reassurance and peace of mind, increased confidence, better sleep, and greater normalcy owing to 'time off' from diabetes demands. More widely, experience of cutting-edge medical technology such as AP systems can serve as a form of transformative 'digital education' for users, in a similar way to notions of 'schools for citizenship' which highlight the political upskilling acquired by citizens who participate actively in local politics. While people with diabetes are often frustrated by the delays caused by clinical trials, there is no doubting the widespread interest in artificial pancreas systems, as illustrated by people with diabetes 'hacking' their own systems. And with future iterations likely to include dual-chamber pumps administering glucagon as well as insulin, intraperitoneal insulin delivery, and integrated multi-function devices incorporating CGM, algorithmic and pump functionalities, medium-term technological developments may transform the treatment of Type 1 diabetes. As the team at Bigfoot Biomedical (an artificial pancreas start-up) put it recently, 'the technology exists to take what is today an omnipresent, dangerous, expensive chronic disease, and turn it into a small nuisance requiring occasional attention.'

The artificial pancreas has clear potential to become a highly significant development in the treatment of diabetes, providing a stepping-stone between conventional intensive insulin therapy and the eventual end-goal of bioengineered and implantable human β cells delivering quasi-physiological insulin in vivo. Nevertheless, this potential will only be realised in full if future AP interventions take account of the manifold psychosocial complexities involved in user interactions with medical technology.