Re-framing type 1 diabetes care through open-source automated insulin delivery: ‘The (expert) patient will see you now, doctor’

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1 | INTRODUCTION

Living with type 1 diabetes is not easy. The unrelenting requirements of daily (and nightly) attention to diet, exercise, stress management and monitoring of blood glucose and other parameters with no ‘holiday’ or break represents a lifelong challenge. Attempts to capture the burden of living with type 1 diabetes include measures of ‘diabetes distress’ which are increasingly being used in clinical trials and even in routine clinical practice. Things that have the potential to reduce diabetes distress include (1) a supportive family with loved ones who know how and when to assist, (2) a healthcare professional team competent and willing to help the person with diabetes make good self-care decisions and (3) diabetes technology. In recent years, diabetes technology has come to the fore with automated insulin delivery (AID) systems (both commercial and open-source) becoming a reality for many people living with type 1 diabetes. Although these systems do not represent a ‘cure’ they are the closest we have come to realising that dream. They have the potential to improve quality of life and help people achieve treatment targets in a way that is difficult with other forms of insulin delivery. In this article, we will explore the potential for open-source AID systems to alter the way that patients and healthcare professionals (in particular doctors) interact. We will look at this through the lens of clinical practice guidelines (the interface between patient, caregiver, regulator and industry) and finally, through the lens of wider society (including issues of equity of access to care).

2 | THE DOCTOR–PATIENT RELATIONSHIP

Traditionally, in medical practice, the doctor has the expertise that the patient seeks out. The flow of information and advice is usually from the doctor/healthcare professional (HCP) to the patient. The relationship that develops is based on trust (on the part of the patient) that the HCP has their best interest at heart and trust (on the part of the HCP) that the patient will follow the advice given. This traditional model still works well for acute episodes of care, but the dynamic is changing in chronic disease management.

When a person is living with a chronic condition, the goals and expectations of treatment are different. The person living with a chronic condition is looking at a long-term (potentially lifelong) therapeutic relationship with the goal being to become as knowledgeable and competent as they can be in the day-to-day self-management of their condition and become less reliant on advice from the HCP. The term ‘Expert Patient’ has sometimes been used...
to describe such a person. Users of AID systems, and in particular users of open-source AID systems, may represent an extreme example of the Expert Patient. Their knowledge and understanding of their diabetes and the technology they use to manage it can be beyond that of the HCP tasked with providing care to them. In a way, their pump, sensor and algorithm have replaced the visit to the HCP providing minute-to-minute ‘advice’ and feedback like no HCP could ever hope to do. We are aware of examples of doctors being sceptical of an individual patient commencing open-source AID use but being ‘sold’ on the idea when follow-up HbA1c levels and time-in-range improve dramatically. While the doctor’s definition of the Expert Patient may be framed around glycaemic control, for the patient it is more about improvement in quality of life and less variability in day-to-day blood sugar levels. It can be quite daunting for some doctors to see a patient whose knowledge about their condition and its management is superior to their own. The flow of advice and the teaching/learning during a consultation with an Expert Patient is two-way. The original terms used to describe open-source AID systems, ‘Do-It-Yourself’ and #WeAreNotWaiting, may have accentuated this different dynamic within the consultation. In order to learn how to help users of open-source AID systems, doctors need to embrace this change in the dynamic within the consultation. Otherwise, they risk adding to the burden (or distress) of the person living with diabetes by denying them the advice and care they seek. Likewise, there is a responsibility on the patient to share knowledge or advice they have received from the diabetes online community with their HCP so an informed discussion can take place around any issues they are trying to resolve.

3 | GUIDELINES AND EVIDENCE

Doctors like to practice (or at least believe they are practicing) evidence-based medicine. Because it is difficult to keep up with the medical literature, doctors often look to clinical practice guidelines to help them distil out of the multiple studies in each area the key recommendations for practice. The American Diabetes Association produces a Standards of Medical Care in Diabetes amounting to a comprehensive and continuously updated set of guidelines for clinical practice. The 2022 version of this document includes (for the first time) a standalone section on DIY Closed Loop Systems. The main message to clinicians from the (very brief) section dealing with this technology is that DIY systems cannot be prescribed (because they are not approved by the U.S. Food and Drug Administration) but that clinicians should assist their patients using DIY systems to ensure that they have a ‘backup plan’ in place if the DIY system fails. This advice is consistent with one of the main tenets of medicine, primum non nocere, or first do no harm. The Professional Practice Committee responsible for writing the ADA Standards of Medical Care is made up of many distinguished healthcare professionals but does not include the patient voice. Before publication, the Standards are reviewed by the ADA Board of Directors which does include lay people.

In the same month as the most recent update to the ADA Standards of Care (January 2022), the Lancet published a paper entitled, ‘Open-source automated insulin delivery: international consensus statement and practical guidance for healthcare professionals’. This remarkable paper is co-authored by 12 individuals, eight of whom have personal experience of using open-source AID systems. It describes the technology (in some detail), covers the (mainly real word) evidence for its use and provides guidance not just for clinicians but also for regulators and medico-legal/ethical experts tasked with deliberating on this disruptive technology and its place in clinical practice. Many of the authors have been part of a European Union funded research consortium entitled the OPEN project which has led the way in user-driven questions (and answers) around use of open-source AID. For anyone interested in this area of practice a detailed review of this document would be time well spent.

4 | SOCIETAL CONSIDERATIONS

The development of open-source AID systems by patients (and parents of patients) living with type 1 diabetes and their widespread use by thousands of people around the world is a remarkable phenomenon. The global network of DIY APS users supporting each other through diabetes online communities may be a sign of how medical care for chronic conditions will be delivered in future. The next challenge for the early adopters and leaders of open-source AID systems is to figure out how this solution can be made more widely available. Many young adults living with type 1 diabetes who might benefit from this approach lack the resources or even the awareness that technical solutions like open-source AID systems exist. Commercial AID systems are becoming more widely available and in many Western countries now most Paediatric patients with type 1 diabetes are using pumps and sensors including hybrid closed loop technology. Will the commercial systems eventually ‘take over’ and make the open-source AID users no longer necessary? Or will the open-source AID community be embraced by more people and grow in strength. The answer to these questions will depend on commercial, regulatory, and societal factors that are likely to be different in different jurisdictions. The phenomenon of DIY APS
raises fundamental questions around equity of access to healthcare and what the role of a health service should be in supporting individuals in their self-management.

Answers to many of these questions concerning closed loop technology will come soon as evidence is generated and adoption increases. Studies will continue to assess the effectiveness of these systems in the real world. For example the NHS is currently undertaking a closed loop system pilot study (n = 1000), to inform a National Institute for Health and Care Excellence (NICE) review. Real-world evidence will lead to more conversations between patients and HCPs about the benefits of different systems (potentially including DIY systems as an option) and how to access them. These conversations will lead to an increase in adoption, with the choice of system coming down to the expertise of the patient and the HCP. Whilst the HCP may not be able to fully support the use of a DIY system in their clinical setting, the DIY community will continue to push the technological boundaries, help patients understand whether closed loop systems are right for them, and shine a light on the evolving nature of the patient-doctor relationship.

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CONFLICT OF INTEREST
LMcM has personal experience of using an open-source AID system.

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