Do-It-Yourself Automated Insulin Delivery: A Leading Example of the Democratization of Medicine

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Mercedes Burnside, MB, ChB¹ , Hamish Crocket, PhD²,
Michael Mayo, PhD³, John Pickering, PhD⁴, Adrian Tappe, BSc⁵,
and Martin de Bock, FRACP, PhD^{1,6}

Abstract

Digital innovations have led to an explosion of data in healthcare, driving processes of democratization and foreshadowing the end of the paternalistic era of medicine and the inception of a new epoch characterized by patient-centered care. We illustrate that the “do it yourself” (DIY) automated insulin delivery (AID) innovation of diabetes is a leading example of democratization of medicine as evidenced by its application to the three pillars of democratization in healthcare (intelligent computing; sharing of information; and privacy, security, and safety) outlined by Stanford but also within a broader context of democratization. The heuristic algorithms integral to DIY AID have been developed and refined by human intelligence and demonstrate intelligent computing. We deliver examples of research in artificial pancreas technology which actively pursues the use of machine learning representative of artificial intelligence (AI) and also explore alternate approaches to AI within the DIY AID example. Sharing of information symbolizes the core philosophy behind the success of the DIY AID evolution. We examine data sharing for algorithm development and refinement, for sharing of the open-source algorithm codes online, for peer to peer support, and sharing with medical and scientific communities. Do it yourself AID systems have no regulatory approval raising safety concerns as well as medico-legal and ethical implications for healthcare professionals. Other privacy and security factors are also discussed. Democratization of healthcare promises better health access for all and we recognize the limitations of DIY AID as it exists presently, however, we believe it has great potential.

Keywords

artificial intelligence, artificial pancreas, automated insulin delivery, democratization of medicine, do it yourself, open-source

Digital technologies ranging from internet connectivity to the application of artificial intelligence (AI) in healthcare have been widely anticipated to contribute to processes of democratization.^{1,2} In this context, democratization refers to the development of empowering, participatory models of engagement.³ Digital technologies are typically valued for making data more readily accessible, for producing new forms of data, and offering advanced, rapid data analysis processes.

The explosion of data within the medical realm challenges the industry to launch into the digital age. However, the existing models of healthcare operate as a closed bio-network of institutions. Topol describes the dominant model of healthcare as an archaic paternalistic approach, arguing that digital innovations offer transformative possibilities for developing a *patient-centered model of care*.⁴ Similarly, the *Stanford Medicine 2018 Health Trends Report* outlines three pillars of democratization of healthcare: intelligent computing; sharing (of information); and security, privacy, and safety.²

Evidence suggests patients are increasingly seeking health information from the internet.⁵ However, despite the growing ubiquity of digital innovations in healthcare, such as digitalized patient health records, these data often remain siloed, accessible only to physicians and acting as a barrier to processes of

¹Department of Paediatrics, Canterbury District Health Board, Christchurch, New Zealand

²Te Huataki Waiora School of Health, University of Waikato, Hamilton, New Zealand

³Department of Computer Science, University of Waikato, Hamilton, New Zealand

⁴Department of Medicine, University of Otago, Christchurch, New Zealand

⁵Department of Software, AndroidAPS.org, Linz, Austria

⁶Department of Paediatrics, University of Otago, Christchurch, New Zealand

Corresponding Author:

Martin de Bock, FRACP, PhD, Department of Paediatrics, University of Otago, Christchurch, 2 Riccarton Avenue, Christchurch 8011, New Zealand.

Email: Martin.debock@otago.ac.nz

democratization. Concerns about the limits of anonymity within public health records^{6,7} and user generated data exist.⁸ Perhaps, more pressing are the emerging concerns of the role of internet technology companies and big data analytics impacting democratic processes around the world.^{9,10}

Despite these challenges facing democratization, there are nevertheless examples that highlight the possibilities of empowering participatory approaches. Indeed, some groups of patients are now equipped with medical knowledge and technology and have collaborated with each other to develop opportunities to truly manage their own health. The so-called “do it yourself” (DIY) automated insulin delivery (AID) innovation is a leading example of this democratization of medicine. In the following, we will describe how the development and application of DIY AID embodies these three pillars of democratization within the Stanford report. We will also explore the implications that this has on diabetes management in general and look to the future as to how this may shape diabetes care.

Intelligent Computing

The Open Artificial Pancreas System (OpenAPS) movement launched by Dana Lewis in 2015 has been fostered by thousands of people with type 1 diabetes worldwide and numbers are burgeoning.¹¹ Technology-driven innovation has boomed, and each successive iteration of innovation becomes more accessible to the layperson. The advent of capable smartphones and accurate continuous glucose monitoring systems has allowed motivated individuals with type 1 diabetes to develop their own software algorithms which allow these devices (including insulin pumps) to “talk” to one another, fashioning the so-called DIY artificial pancreas system (APS) or “closed loop” system. Such a system has the potential to reduce the cognitive burden associated with laborious diabetes tasks, hence improving quality of life for those living with type 1 diabetes. Over time, two core algorithms (OpenAPS and Loop) have emerged as the preferred algorithms. These algorithms and the other, combined with technology aids that allow communication between the devices and interact with the user (OpenAPS,¹² AndroidAPS,¹³ and Loop¹⁴), demonstrate intelligent computing.

Intelligent computing in the democratization of medicine is classically described as the coupling of AI capable of processing vast data sets such as DNA banks with automation.² However, machine learning (ML) algorithms (a subset of AI) are not necessary for democratization of medicine. Expert systems and well-specified algorithms derived with traditional statistical approaches may produce better results, at least on smaller data sets. Nevertheless, despite the hype of expectations and the likely more limited use of AI, it is set to produce a wealth of new techniques which lead to more precise and personalized prediction tools.¹⁵

In the DIY diabetes sphere, intelligent computing is an example of the symbiosis between algorithm and human

intelligence. On one hand, the system uses a heuristic algorithm that estimates the glycemia projection every few minutes based on the current glucose level, insulin doses, carbohydrate consumption, and personal configuration and adjusts insulin dosing automatically based on an analysis of these data. However, as the user experience has grown and been shared (the second pillar of democratization of medicine), developers have further refined the algorithms to improve functionality and user outcomes.

While the DIY APS example demonstrates heuristic reasoning, it is not truly representative of AI and ML in particular as the currently implemented algorithms are not capable of learning from past data collected from the patient and past insulin dosing actions (both correct and incorrect) taken in order to improve the system’s own predictive and decision-making performance. Although the heuristic method currently used in OpenAPS is reasonably effective, there is merit in considering other options that may further enrich the systems performance, and the wide range of users provides an excellent base for testing new ideas.

The current research in the field of intelligent computing for artificial pancreas technology actively pursues the use of ML for two main tasks: First, for predicting blood glucose levels ahead of time, which can be useful for generating alerts such as impending hypoglycemia warnings. Approaches use a range of ML techniques such as neural networks, in conjunction with various possible inputs, ranging from blood glucose sensor readings alone through to comprehensive input data embracing blood glucose sensor readings, carbohydrate intake records, insulin bolus records, and patient activity details.^{16,17} It is currently unclear which permutation of ML techniques and input data is best, and to this effect, work continues in this area although the lack of a large standard dataset for testing is an issue.

The second application of ML is in the optimization of insulin dosing strategies. For example, Chakrabarty et al combined a deep learning system for estimating the macronutrient content of food derived from smartphone images with an open-loop artificial pancreas.¹⁸ The macronutrient estimates were used as one of the inputs to the system’s insulin dosing algorithm in order to maintain blood glucose levels in target range. Daskalaki et al afford another illustration of this as they utilized reinforcement learning (a type of ML focused on selecting actions to maximize rewards) to optimize basal insulin rates and the insulin-to-carbohydrate ratio based on an individual patient’s glycemic profile.¹⁹

Machine learning, while currently in fashion in the intelligent computing community, is not the only approach to AI. A significant portion of AI’s history has concerned knowledge representation in a symbolic or mathematic form, and the elicitation of knowledge from experts. For example, the early AI systems were designed after interviewing medical practitioners to obtain rules for disease diagnosis. Approaches stemming from this alternative view of AI have also been

developed in the artificial pancreas community, but they are far less common than the ML approaches. A notable example is the fuzzy logic controller developed by Mauseth et al.²⁰ where insulin dosing decisions are determined by the current blood glucose level, the most recent change in blood glucose levels (ie, glycemic velocity) and the most recent change in the change of the blood glucose levels (ie, glycemic acceleration). These three values are inputs to a fuzzy logic procedure that calculates the correct amount of insulin for the patient. The procedure itself was derived from a table of insulin doses obtained from endocrinologists and is thus based on expert knowledge and experience rather than learning from data. Overall, this approach was found to be surprisingly effective.

It is also worth mentioning that hybrid AI systems consisting of both a learning component and an expert-derived component are certainly possible. Many ML approaches by design are interpretable. For example, a decision tree is a type of model that can be learned from data, but it can also be inspected and understood by a human since the decision tree itself is basically a set of if-then rules. Therefore, the knowledge discovered from the data can be verified by medical experts. In contrast, other approaches such as neural networks cannot be so easily inspected, which has the potential to conceal errors and biases in the ML model.

In essence, various AI techniques and approaches exist that have been tested in conjunction with APS. Many have been clinically validated albeit often in small cohorts, and many of the algorithms are easily obtainable as open-source software. Importing these ideas into DIY AID will likely be a fruitful endeavor to further democratize medicine by providing more options to patients.

Sharing of Information

Sharing of information symbolizes the core philosophy behind the success of the DIY AID evolution. The code for each system is open-source, so is freely available via the internet.²¹ The current impression for many people with type 1 diabetes, and indeed healthcare professionals, is that transitioning to a DIY automated system requires the user to be technologically savvy. Yet, many people successfully adopt DIY AID without having a technical background.²² The sharing of data and experiences is one way to overcome the technology barrier. The online community can endow support to one another from the building of their own DIY system, through to troubleshooting. Furthermore, online forums have been established with the goal of offering social and emotional support in addition to technical support, as well as celebrating the successes of the community.²³ Unlike the clinic forum, this support can be sought 24 hours a day because of the global spread of users, however, as a community of volunteers there can be some variation in how quickly assistance is provided.

Despite operating as a peer-to-peer community, the DIY APS has sought to openly engage with medical and scientific

communities. Real world data, user experiences, and new research are shared at the highest academic forums and research collaborations featuring DIY innovators alongside traditional medical researchers have been formed. Moreover, the community has developed a tool, the OpenAPS Data Commons, through which users can share their glycemic data with researchers.¹¹ This sharing draws parallel to Dr Topol's concept of Massive open online medicine (MOOM) where thousands of individuals voluntarily contribute their de-identified medical data to a massive cloud-based database from which consumers, physicians, and researchers can examine health information and outcomes based on terabytes of data.⁴

Sharing of data is essential for the development of new AI and ML techniques for APS because data are needed for both learning predictive models and validation processes. In contrast, when data are withheld (eg, for commercial reasons), progress is hindered because scientific reproducibility becomes impossible.

While open and transparent data sharing has been a principal driver behind the success of DIY AID systems, this is in direct contrast to the usual method of knowledge transfer between healthcare professionals and patients. For example, the DIY model mandates that the community of patients afford knowledge and support to new and existing users as healthcare professionals harbor little or no knowledge on the algorithms or how to personalize settings. This contrasts with orthodox medical models where healthcare professionals possess the expertise. It is not surprising then that open-source diabetes technology poses an ethical dilemma for treating physicians who are faced with the challenge of safeguarding the therapeutic relationship while not endorsing DIY systems. This avant-garde approach is also associated with medico-legal risks as the open-source, noncommercial software has not been formally tested and has no regulatory approval.^{24,25} The ethical quandary mainly focuses on the implications of being an accomplice to a nonregulated therapy (and hence safety), but it also relates to concerns regarding security and privacy—all being the third pillar of the democratization of healthcare.

Security, Privacy, and Safety

Whereas the first two pillars (intelligent computing and sharing of data) have been driving forces behind the development of DIY AID systems, the third pillar, security, privacy, and safety, is different in that it must be respected for democratization of healthcare to be successful.

Security, privacy, and safety continue to be a concern for those who are skeptical of the DIY community, however, there are several redeeming features. For example, real world data reveals remarkable glycemic outcomes,²⁶⁻²⁹ and there are several studies being conducted or planned that will add safety and efficacy data.³⁰ Democratization challenges traditional medical understandings of confidentiality. In this democratized era, the greatest benefits stem from information sharing,

however, this translates to a privacy threat. Maximizing the potential of patient data while preserving privacy should remain at the forefront of the DIY community. Nevertheless, it is still up to the individual to decide whether to contribute their personal glycemic data (de-identified) to the OpenAPS Data Commons. In contrast to commercial systems, the individual is sole owner of her/his data; full functionality to use the systems, including statistics and reports, is available without giving a device manufacturer access to the data. With respect to security, this comes down to integrity of the insulin pump, the smartphone, and additionally, the cloud servers used to store the data from the devices, if users have enabled sharing. There are reports showing that older insulin pumps commonly used in DIY APS can be “hacked” and deliver erroneous insulin doses in a malicious manner,³¹ which indeed has led to the recent Food and Drug Administration recall of older Medtronic insulin pumps.³² Although this may appear to be a grave risk, hacking requires both an insulin pump’s serial number and being within a few meters of the insulin pump. To date, there are no reported cases of intentional harm or personal data breaches and new additions to the portfolio of pumps that can be used in DIY APS are not susceptible to this attack vector. With respect to cloud storage, a compromised server could potentially lead to data being copied elsewhere (not what the patient agreed to) or even the patient’s identity being determined (eg, via an email address linked to the data). Standard best practices for securing and storing sensitive information should therefore be followed by the community.

The DIY community represents a diminutive portion of the global population of people with type 1 diabetes, the part sharing their data for research yet a smaller group. To this effect, significant headwinds are a requisite for the spread of this democratization. This is partially due to difficulties in accessing the technology required to successfully build a DIY system, although other aspects are important. Fundamentally, democratization demands openness, and some patients remain ambivalent about sharing personal data despite their desire for better care. Thus, the DIY community must invest in vigorous cybersecurity and anonymization processes to mitigate these security concerns and impart confidence to the patient. Additionally, users may be reluctant to share their chosen mode of treatment as they fear that the information could compromise insurance coverage or the relationship with their healthcare professional. Resistance to change by healthcare professionals and people with type 1 diabetes may be perceived as a battle between automation (particularly AI) and humankind—with concern that AI will lead to physician’s deskilling or even succumbing to machines³³ because not only does AID replace the patients day to day work but the open-source and DIY nature of the system may strip away physician responsibility also. In general terms, trust is a critical factor to adopting automated systems and AI in particular, and it needs to be built between healthcare professionals, data scientists, statisticians, users, and the technology at hand.³⁴

There is no denying and we are on our way to a democratized healthcare system. A number of medical specialties are undertaking research in the field of algorithm development and AI and are developing tools that will facilitate democratization, many of which are in their infancy. However, DIY AID systems based on traditional methods to predict changes are relatively established. In time, it may seem absurd that we once sought an opinion from a single physician compared to the community learning epitomized by the DIY diabetes community.

One of the societal forces propelling the democratization of healthcare is the promise of improved access to healthcare for all. On the one hand, the open-source innovation of the DIY APS mitigates some of the difficulties individuals may have in accessing diabetes technology as the existing insulin pump companies create barriers to the DIY approach and commercially available AID systems are prohibitively expensive, and limited to countries with extensive private health insurance or healthcare subsidy.

However, we appreciate that the realization of a DIY system demands a certain degree of enthusiasm as well as a base level of knowledge from the individual which may preclude some people with type 1 diabetes taking up this technology which goes against the theory behind healthcare democratization.

Despite this, we propose that open-source DIY AID is a leading example of healthcare democratization based on intelligent computing; sharing of data; and safety, security, and privacy. Not only has sharing of data led to the innovation of diabetes algorithms (capable of improving diabetes outcomes) but the innovation and expertise stems from the diabetes community rather than healthcare professionals, scientists, or pharmaceutical companies. This embodies the ultimate patient care model, putting an end to the age of paternalism.

A sea of change is on the horizon as the democratization of healthcare comes to fruition. Several challenges of scale lie ahead including how regulatory authorities will respond to this revolution in innovation and translation of medical therapy, how law-makers and indemnifiers will advise healthcare providers, and finally, how to game the entire medical system to embrace the potential for rapid patient driven innovation.

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ORCID iDs

Mercedes Burnside <https://orcid.org/0000-0002-8414-4479>

Martin de Bock <https://orcid.org/0000-0003-0454-6679>

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