Do-It-Yourself Diabetes Management: Perspectives of a Patient, a Physician, and an Ethicist

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Evolving patient empowerment and education have produced communities of do-it-yourself (DIY) medical device makers and hackers who value their autonomy and, in at least some cases, achieve excellent results. Physicians may find themselves left out of what was once a cornerstone of an ancient and traditional relationship.

Here, we present perspectives on DIY artificial pancreas systems (1,2) from a patient (K.D.), a physician (J.M.S.), and an ethics professor (K.W.G.). Our intention is to convey the patient's and the physician's personal feelings regarding DIY closed-loop insulin delivery devices and the DIY initiative that fostered their development. These views could well be representative of some other patients and physicians, but certainly not of all. From a less personal perspective, the ethics professor reflects on the potential societal impact and consequences (both positive and negative) of the DIY device. An empirical assessment is outside of the intent and scope of this article.

Patient Experience (K.D.)

Having been diagnosed with type 1 diabetes >12 years ago, I am familiar with the constant monitoring and adjusting that is required to maintain optimal blood glucose levels and have learned that even the most diligent of patients cannot achieve optimal glucose control all of the time. I consider myself to be a motivated and reasonably technology-savvy individual, but I was dissatisfied with my blood glucose control.

To achieve better glycemic control, I, like thousands of other people with diabetes, turned to social media to learn about others' experiences in managing their glucose levels. I quickly realized that social media has become a 21st-century public commons for all things related to type 1 diabetes. Individuals with the disorder create support groups and write blogs in which they share tips and tricks to more effectively manage blood glucose levels.

It was social media that led me to discover DIY closed-loop insulin delivery systems, which had existed for several years by the time I heard of them. The moment I learned about the existence of such DIY systems, I knew I had to have one. I thought I would be a good candidate; I was educated, followed by clinicians who are involved in forward-thinking research, connected to an academic medical center, mindful, and compliant. Within 1 hour of learning about "DIY looping," I had joined the Looped Facebook group and conducted preliminary searches on Google, looking for guidance.

DIY closed-loop systems are a homegrown approach to type 1 diabetes management that links a continuous glucose monitoring (CGM) device and an insulin pump via an algorithm to automate insulin delivery. As of 4 March 2019, >1,161 closed-loop systems had been created by patients, apparently to good effect, at least anecdotally. Patients using such systems report fewer high and low blood glucose levels, more glycemic time in range (a CGM-derived metric of the time spent with glucose levels of 70–180 mg/dL), and reductions in A1C (3). The artificial pancreas system described on the OpenAPS website (3) comprises six components: insulin pump, CGM device, open-source hardware device that uses Bluetooth for wireless communication, smartphone, computer, and software for developing an application (app) for the phone.

Creating a DIY artificial pancreas requires building a personalized app that acts as a bridge between the insulin pump and CGM device. The code to build such an app is available online as a free download (4). Once the app is installed on a compatible phone, the user's personal settings are entered to customize the system. Users enter their pump serial number, CGM transmitter identification code, and insulin profile, which includes

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correction factors, suspend thresholds (glycemic values at which automatic insulin delivery will be suspended), insulin-to-carbohydrate ratios, basal insulin infusion rates, and insulin sensitivity factor.

Users can then watch in real time as the personalized app's algorithm predicts their future blood glucose levels and adjusts basal insulin accordingly. Parents and caretakers can even monitor and intervene remotely through integration with an online tool to view users' blood glucose levels, carbohydrates consumed, and insulin delivery. Continued use of the system allows users to fine-tune settings, better estimate carbohydrate intake, and obtain tighter glucose control. The online tool is provided by Nightscout (5), a Web-based user group/community with the catchphrase "#WeAreNotWaiting." Nightscout also provides a series of data and reports that display users' total daily insulin and calculates average glucose and estimated A1C levels (Figure 1).

Many DIY Loopers pay out of pocket up to $1,200 for an out-of-warranty Medtronic insulin pump and RileyLink (6), a piece of hardware that bridges low-energy Bluetooth from an iPhone to a radio frequency that the insulin pump uses, facilitating communication between devices. I was fortunate to befriend a woman in the Looped online group who had built the system for her young son and experienced great success. She had been given a backup pump by a friend and wanted to pass it along to me without charge. I paid $100 for a RileyLink and received both pieces of equipment within 1 week. Because I already used a CGM system, iPhone, and Macintosh computer, these were the only components I needed to acquire.

I followed online instructions to build the system and test my settings, and, after a few weeks, began to appreciate how much my quality of sleep improved and my diabetes-related stress decreased. Before using the DIY closed-loop system, I had good glycemic control, with

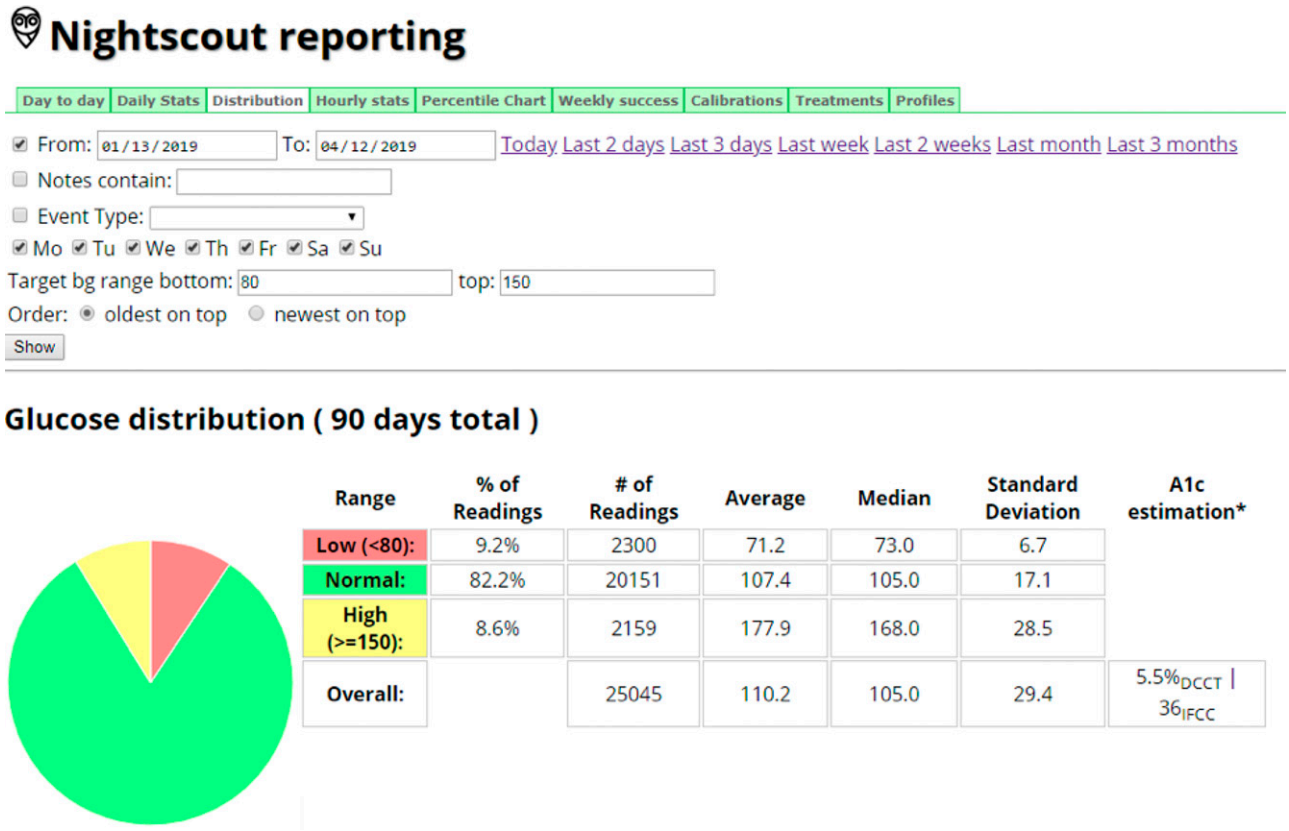

FIGURE 1 A Nightscout report showing a summary of K.D.'s glucose data for a 90-day period. The first column is divided into low, normal, and high blood glucose value parameters as set by the user. The second and third columns show the percentage of time a user experienced low, normal, or high blood glucose values and the raw number of readings in each category during the selected time period. The remaining columns show the glucose means, medians, and SDs in each category. The final column shows the user's estimated A1C, based on DCCT (Diabetes Control and Complications Trial) and IFCC (International Federation of Clinical Chemistry) standardized reporting methods.

A1C values in the range of 6–7%. However, I experienced extreme alarm fatigue and diabetes burnout as a result of being bombarded with alerts from my CGM system, which felt like every 5 minutes because of persistent high glucose levels.

The DIY Loop system has allowed me to focus less on diabetes while achieving better glycemic management. After 8 months of using a DIY artificial pancreas system and adjusting my settings, I had an A1C of 5.4%, which is in the range a person without diabetes would have. I have had more confidence in my diabetes self-care skills, less diabetes-related anxiety and fear of hypoglycemia, more energy throughout the day, and, quite literally, I sleep better at night.

Physician's Perspective (J.M.S.)

I followed K.D. for type 1 diabetes throughout most of her college years and for a short time thereafter. During that period, she was consistently attentive to managing her glucose levels with the use of a CGM sensor and an insulin pump. Her diligence resulted in A1C values mostly within the range of 6.5–7.0%; however, she had hypoglycemic episodes, and serious ones were always a fear.

K.D. and I continued to communicate after she was "graduated" from my care to that of another physician. One day, she excitedly related that she had been participating in a DIY initiative for type 1 diabetes, which made it possible for her to put together the elements of a closed-loop system. She explained how this could be done and then showed examples of her daily glucose excursions. I was amazed. Her glucose levels were mostly normal, and—importantly—hypoglycemia was much less of an issue. K.D. was being followed by an excellent diabetologist, who certainly contributed to the improvement in her glycemic management. However, having glucose levels in the normal range, with only small glucose excursions and the absence of hypoglycemia, had been rare for her in the past. It was clear to me that the DIY closed-loop system offered K.D. significant benefit.

When K.D. informed me of her success with the DIY closed-loop system, a commercial automated insulin delivery system had already become available, and others were being developed. All were undergoing the rigorous scrutiny required to achieve U.S. Food and Drug Administration (FDA) clearance. It took some time for me to process the idea that a community with a passion for improving the health and well-being of individuals with diabetes could have developed a treatment algorithm so quickly and seemingly effectively, while bypassing the process for FDA review.

After my interaction with K.D., I considered how I might have responded if I were still her diabetologist. How would I have reacted to her acquisition of a DIY closed-loop system and her obvious success with it? How could I have been sure that the system would not have a flaw leading to bad outcomes? If I had chosen to work with K.D. and her new system, would I have been helping or possibly endangering her? Remember that this was not a simple over-the-counter treatment; at the time she began using her DIY system, it was an alternative, complex system for managing diabetes that had not undergone FDA review.

I believe I would have been happy for her, but perhaps also uncomfortable. I had always understood that an interactive approach with patients was optimal for the management of type 1 diabetes. Because patients are often well informed and had first-hand knowledge of the factors affecting their glucose patterns, it is important to take their input and suggestions into account. However, K.D.'s demonstration of her skill, know-how, and success was different. It was clear that she, and a growing percentage of other patients, could optimize glucose management themselves, with minimal input from a physician. If I had still been K.D.'s physician, I would not have been calling the shots, literally or figuratively. It was clear that physicians would need to adjust to a new reality.

Some time ago, I was on the phone with a diabetologist colleague. She lived with type 1 diabetes herself for many years and had expertise from both patient and physician perspectives. When she related that she still had troubling hypoglycemia, I asked whether she was aware of DIY closed-loop systems. She responded that she knew little about them. I then told her about K.D.'s success and suggested that K.D. would probably be happy to discuss it with her. My colleague responded positively to that suggestion, and with K.D.'s approval, I provided contact information. I then realized the irony of my former patient educating my diabetologist colleague about type 1 diabetes management. The type 1 diabetes world was changing before my eyes.

Ethicist's Perspective (K.W.G.)

The most interesting and difficult challenges in medical ethics are elicited and shaped by new technology. From solid-organ transplantation and gene editing to extracorporeal membrane oxygenation and computerized

decision-support systems, the technological challenges facing patients, clinicians, and society have never been greater. DIY closed-loop systems for diabetes management are an example of something slightly different—direct patient initiation, implementation, and management of a new technology with, as we saw, its own hashtag reflecting the times: #WeAreNotWaiting. What is it that patients with diabetes are not waiting for? Apparently, something that is both unremarkable and yet not provided easily by standard or traditional medical management: fine-grained, patient-structured glucose monitoring and management.

With the advent of DIY closed-loop insulin delivery systems and other DIY patient tools, we might be witnessing the beginning of an era in which patients appear to know more about the details of their particular maladies than their physicians or other members of their health care team. This is not an issue of a patient reading widely, learning a lot, and showing up for an appointment with a stack of daunting printouts. It is more about patients themselves performing assays, calculating appropriate interventions, and delivering their own therapies. Use of these systems might represent the first widespread, patient-structured response to a chronic malady.

There is apparently no precedent for patients and only patients *1*) monitoring a laboratory value, *2*) calculating a correct intervention, and *3*) delivering it. It is perhaps not surprising that such a change would occur in diabetes treatment and management; people with diabetes have taken responsibility for self-monitoring of blood glucose for a half-century and, since the mid-1970s, many have also handled their own insulin delivery via an insulin pump. There are few, if any, good arguments against increased health literacy and the inclusion of patients as partners in health monitoring, improvement, and treatment; still, the growth of DIY medical devices and interventions warrants special scrutiny. There are several reasons for this, and each has an ethical component.

First, it is unknown whether DIY devices and modifications are safe. We have very good reasons to require that society test and assess drugs and devices before they are used on or in people. DIY devices sidestep such assessment. (Nevertheless, even as governmental device-testing processes should perhaps be nimbler and more proactive, shortcomings in that process do not undermine the importance of patients' desires to contribute to the management of their own maladies.) Moreover, there are markets for used DIY components, and insulin pumps regarded as out of date in North America are still available for sale in Europe. Thus, the FDA in May 2019 issued a formal warning about DIY closed-loop systems, stating: "When patients combine devices that are not intended for use with other devices, or when patients use any unauthorized devices, new risks are introduced that the FDA has not evaluated for safety or effectiveness. Patient use of unauthorized diabetes management devices, alone or along with other devices, could result in inaccurate glucose level readings or unsafe insulin dosing. These inaccuracies may lead to injuries requiring medical intervention, such as severe low blood sugar, coma, diabetic ketoacidosis (buildup of acids in blood), and death" (7).

Next, it is unclear what effect the evolution of DIY medical devices will have on physician-patient relationships. We hypothesize that some—perhaps many—physicians and other members of the health care team do not know their patients are using such devices. Correctly enshrined as an essential part of the foundation of high-quality medical practice, the doctor-patient relationship might erode or even cease in an environment shaped by patients who make or modify their own devices. The need for valid or informed consent is an uncontroversial cornerstone in medical practice. Its components—adequate information, voluntariness, and capacity—cannot be vouched for if there is no formally trained partner to answer questions as part of the process.

Third, from electronic health records to mobile health apps, the health care community seems to be completely unaware of or uninterested in the challenges posed by freelance, laissez faire, and ungoverned software writing. There are no known standards or requirements for accountability in the world of biohacking. Although a physician need not always know enough molecular biology to assess the appropriate use of a drug he or she is prescribing—external standards for testing and oversight are reliable, at least often enough—the computer code undergirding DIY devices is utterly opaque. To be sure, what the World Health Organization calls "self-care" can be a valuable tool for improved health, perhaps especially in resource-limited populations (8). Although, this, too, raises large and tricky empirical questions and already has challenged and will continue to challenge clinicians and public health authorities (9); there is no credible basis for opposing demands for rigor in research, testing, and governance.

Conclusion

Insulin management is not the only health care service being reimagined and hacked by patients. From cervical

cancer screening (10) to bronchodilator therapy (11) and vision testing (12), patients are, for many reasons, seeking to broaden their control over their own treatment. Indeed, patients can now order online laboratory tests for sexually transmitted infections, various disease titers, fertility assessment, and other purposes. The state of Arizona has approved legislation that permits patients to order their own laboratory tests directly. One can even buy a CRISPR/Cas9 gene editing kit from several vendors.

DIY closed-loop systems evolved as a means to support affordable and nimble blood glucose management. The use of these systems is expanding; yet, such systems are not formally tested or evaluated, their use is not governed, and their effectiveness has not been scrutinized. Anecdotal reports by users such as author K.D. and admiration by seasoned and senior physicians such as author J.M.S. suggest that such systems can be a useful, patient self-managed technology for diabetes treatment. We are in some sense witnessing a gradual shift in the standard of care for diabetes, albeit without the customary processes that govern device development, approval, and use.

Diabetes has been known in one form or another for millennia, apparently beginning with what ancient Egyptians in 1500 BCE called *madhumeha* or "honey urine" because the urine of those affected attracted ants. Any improvement in patient self-care and management should be welcomed. However, such a welcome should also hew to well-established, evidence-based standards and processes that provide confidence when we introduce new drugs and devices to the armamentarium—no matter whose armamentarium it is.

DUALITY OF INTEREST

No potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

All of the authors took part in planning and writing the manuscript. J.M.S. is the guarantor of this work and, as such, had full access to all information presented and takes responsibility for the overall integrity of the article.

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