Journal of Diabetes Science and Technology
2020, Vol. 14(2) 195–197

DOI: 10.1177/1932296820901612
journals.sagepub.com/home/dst
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Certified Interoperability Allows a More Secure Move to the Artificial Pancreas Through a New Concept: "Make-It-Yourself"

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Type 1 diabetes (T1D) is among the toughest health condition to manage both by the affected patients and by the healthcare professionals (HCPs) who assist them. While evidence-based recommendations are to make all efforts to reach near-normal glucose levels to prevent long-term complications related to glucose toxicity, recently reported registries have shown how few patients with T1D succeed in getting the 7% (53 mmol/mol) A1c target.[1,2] The key challenge is to avoid hyperglycemia without increasing hypoglycemia, which has been integrated in the International Consensus based on continuous glucose monitoring (CGM) as the goal of keeping glucose for more than 70% of time in the 70-180 mg/dL range with less than 4% of time below 70 mg/dL including less than 1% below 54 mg/dL.[3] The variability of insulin needs in daily life results in a "Mission: Impossible" for most human brains to adjust insulin delivery to glucose variations in order to maintain glucose levels in a safe near-normal range. The availability of increasingly accurate glucose sensors for CGM and reliable insulin pumps since the beginning of the second millennium has revitalized the concept of automated insulin dosing according to current and predicted glucose changes thanks to control algorithms targeting at close-to-normal glucose levels.[4] Several pioneering consortia of control engineers, digital scientists, and diabetes clinicians have investigated combinations of CGM systems, insulin delivery devices, and control algorithms from the secured hospital environment to real-life conditions which allowed demonstrations of safe, effective, and usable closed-loop glucose control. Improvements included increased time in the 70-180 mg/dL glucose range, reduced time in hypoglycemia, lower average glucose and A1c levels, and reduced diabetes care burden.[5] Recently reported trial results showed close to 80% time in range at night-time, a time period during which hypoglycemia is highly feared.[6,7] Nevertheless, full automation does not allow optimal control at mealtime due to delayed action of subcutaneously delivered insulin, resulting in the concept of "hybrid" closed-loop systems with meal announcements for anticipated insulin bolus before food intakes.[8] Due to the needed safe connections between the devices to minimize the risk of losing the signal between CGM, algorithm, and insulin infuser, closed-loop systems, commonly designated as "artificial pancreas" (AP), have been locked through specific communication codes. In September 2016, the US Food and Drug Administration (FDA) gave the approval to sell the first hybrid closed-loop automated insulin delivery device, the MiniMed 670G, for people with T1D.[9] Of note, for the sake of safety, patients needed to calibrate sensor signal 4 times per day and correction bolus were not included in the algorithm features. Annoying sensor alarms and frequent exits of auto mode have somewhat disappointed early adopters as recently reported.[10]

This long road to get an approved AP system contrasting with the widespread use of insulin pumps and CGM devices in the T1D population on one side, and the ability of algorithm freelance designers to create and make easily accessible glucose controllers, such as OpenAPS, AndroidAPS, or Loop on the other side, resulted in the birth of the "Do-It-Yourself" (DIY) community.[11] Thanks to open communication with some pump models and tricks to hack CGM signal so that the AP app could drive the insulin infusion based on CGM data; DIY patients have reported dramatic improvements in glucose control with the support of the DIY community. Miscellaneous reactions of HCPs confronted to #We Are Not Waiting patients have emerged from admiration toward skillful engagement to obtain better care to fear of taking any responsibility in assistance to T1D mavericks. Warnings have been sent due to the risks of using non-certified device combinations, especially after the occurrence of severe events.[12]

The recent authorization by the FDA of the first interoperable automated insulin dosing controller, Tandem Diabetes Care Control-IQ technology, appears as an outstanding response to the patient wish of "making their own AP" while

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setting the conditions of safety and efficacy for a control algorithm which can be used with various device combinations.[13] The approved algorithm has shown, through a large number of clinical trials, including the recently published DCLP3 trial,[14] the benefits obtained by its unique features: (1) automated insulin correction boluses administered using CGM-based patient state estimation; (2) a dedicated hypoglycemia safety system that attenuates smoothly, or discontinues, insulin delivery using CGM and insulin on-board information; and (3) gradually intensified control overnight, sliding the algorithm target down to achieve blood glucose levels of approximately 100-120 mg/dL by the morning.[15] This FDA approval opens the door for an assessment of the features of any control algorithm in terms of safety and effectiveness in glucose control with a reference to "a well-identified special control".

Another major expected outcome of this FDA approval is a push toward the development of new pump and CGM models which will meet alternate controller-enabled insulin pump (ACE) and integrated CGM (iCGM) criteria, respectively.[16,17] These hopefully forthcoming devices will be immediate candidates to be connected to an interoperable automated insulin dosing controller. This new world will not suppress the "deals" between the manufacturers of ACE pumps and iCGMs and developers of certified interoperable controllers for allowing the 3 components to "speak" to each other. But by refusing the deal, a manufacturer of one of these components will hurt himself by blocking his participation in the expanding field of closed-loop insulin delivery.

The next question is about the future of DIY fans. Will they survive in this legally open world? Why going on using rather old pump models, hacking or transforming CGM devices and signals, and struggling with unstable connections to non-certified algorithms? How arguing with HCPs they have better using fiddled montages when interoperable certified devices and algorithms are available? Because they are fond of customization and a continuous source of new ideas that can improve usability and further reduce care burdens, DIY community members will not—and should not—disappear. To prevent the dinosaur fate, they will have to convert to a "Make-It-Yourself" concept. This concept will consist of the personal selection of the most-friendly certified components of the automated insulin dosing system they wish for themselves. Thanks to eagerness for optimization, this updated community is expected to generate demands for further innovation such as more convenient and individually tailored man-to-machine interfaces or additional options for multisensor inputs according to individual needs.[18]

FDA approval of the first interoperable automated insulin dosing controller is a giant step by allowing a more secure move to the AP while opening the door to the liberty of "Make-It-Yourself".

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) received no financial support for the research, authorship, and/or publication of this article.

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