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Smart Pens Will Improve Insulin Therapy

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Worldwide, pens are the most widely used devices for delivering insulin.[1] This is not surprising given that compared to syringes/vials for insulin administration pens are more convenient, have better dosing accuracy, and are associated with improved adherence and persistence and less hypoglycemia risk. They are also preferred by people with diabetes requiring insulin.[2] However, in clinical practice information on both insulin dose and timing of injection are invariably missing, incomplete, and/or inaccurate. This lack of accurate documentation of insulin therapy is a significant barrier to optimizing glycemic control for individuals using pens. It is also noteworthy that, at present, no national or international clinical practice guidelines explicitly recommend insulin dose logging.

The First FDA-Approved Smart Insulin Pen

On December 14, 2017, the first FDA-approved smart pen for insulin was launched.[3] This device can record the amount and timing of each insulin dose and wirelessly transmit the information via Bluetooth to a dedicated mobile app. This associated smartphone application (app) also tracks insulin-on-board, makes dosing recommendations, and prepares reports for health care professionals. Other similar smart pens with these capabilities are likely to receive FDA approval soon. It is only with the introduction of smart pens that the majority of insulin users and professionals (as opposed to pump users and those currently using separate insulin bolus calculators) will at last have access to important clinical data on insulin administration to assist with individualizing diabetes management.

Barriers to Effective Use of Insulin

Currently there are three important barriers to effective use of insulin, where introducing smart pens is likely to be beneficial:

- Poor adherence and insulin omission: Missed insulin doses can occur for a number of reasons including simple forgetfulness, embarrassment, dose complexity, financial cost, and deliberate omission for the purpose of weight control.[4] Having access to insulin data will provide opportunities to clinicians to conduct more informed discussions with insulin users and the smart pen app can potentially provide patients with simple reminders in the case of missed doses.
- Inadequate insulin initiation and intensification: Mobile apps with algorithms to support insulin dose calculations and adjustments for achieved glucose levels with feedback from accurate measurements of the amount and timing of insulin will have the potential to overcome clinical inertia, which is seen commonly in type 2 diabetes.[5]
- Danger: Insulin has been associated with more medication errors than any other class of drugs particularly in hospitals.[6] Automatic access to dosing and timing of insulin administration information will allow for effective root cause analyses of in-hospital errors to reduce in-hospital insulin dosing errors[7] and thus facilitate safer insulin use.[8]

By providing automatically uploaded and analyzed insulin dosing information, smart pens will have the potential to support adherence to treatment plans, appropriate dosage decisions, and accurate dosing. These benefits of smart pens will be particularly useful in specific clinical settings that are presented in the Table 1.

Barriers to Adoption of Smart Insulin Pens

At the same time, like all new medical technologies, each new smart pen will have to demonstrate in real-world settings specific improved clinical outcomes, patient-reported outcomes regarding quality of life, product costs or savings,

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Table 1. Clinical Settings Where a Smart Pen Will Likely Be Beneficial.

Starting insulin where there are concerns about hypoglycemia and/or excess weight gain
Where hypoglycemia is a recurrent problem or where there is hypoglycemia unawareness
Those with frequent episodes of uncontrolled diabetes requiring unscheduled visits to health care providers
Those with glycemic variability causing psychological distress
Where forgetfulness is frequent or when deliberate insulin omission is suspected
Those whose numeracy undermines dose calculations or who tend to give similar doses for very different meals
Children with type 1 diabetes and older insulin treated individuals living on their own
Women with gestational diabetes requiring insulin

and costs of training (if any) so that a realistic economic analysis can be developed. For this new smart insulin pen technology to be widely adopted, it will need to satisfy both and human factors usability engineering and health economics analyses.[9]

Many new technologies for diabetes have been widely adopted more slowly than their developers expected, such as, for example, insulin pumps (compared to multiple dally injections), continuous glucose monitors (compared to self-monitoring of blood glucose), and insulin dosing mobile apps (compared to pen-and-paper algorithms). Technology inertia might also be a barrier for widespread adoption of smart pens, but the human factors of these products (compared to traditional pens) will likely be much more similar than the behavior changes that were needed for adoption of the three aforementioned diabetes technologies.

The Future for Smart Pens

In the future clinicians will be working within a "Digital Diabetes Ecosystem" that combines the Internet of Medical Things (connected physiological and behavioral sensors embedded within multiple medical devices worn or used by an individual) and the new smart pens to support insulin therapy with continuous access to the Internet.[10] We expect that insulin dosing data combined with real time continuous plasma insulin data,[11] together enhanced with the use of artificial intelligence and machine learning to support dose calculations, will eventually predict and prevent adverse events such as hypoglycemia. These predictions will be possible at a much earlier time when an intervention is more likely to be successful.[12] As a consequence we expect that smart pens will replace "dumb" insulin pens that lack sensors, transmitters, and the capability to integrate with other diabetes data collecting systems. Sound cybersecurity of these connected diabetes devices, including these new smart pens, will be necessary to maintain confidentiality, integrity, and availability of data. DTSec, the first consensus standard for network-connected diabetes device cybersecurity, already specifies security requirements and a program for assessing conformity to those requirements.[13]

Despite insulin having been available for almost a century it is only now that insulin users and professionals will have access to accurate information on how much of and when a dose of insulin was given, unless an insulin pump was used. The cost and amount of effort needed to operate an insulin pump are considerably more than for an insulin pen. Uptake of pumps in T1D has been reported to range from as little as 12% in Europe to 40% in the United States[14] and for T2D (the majority of insulin users), uptake of pumps has been exceedingly low. Smart pens may be very useful for people who do not start pump therapy because of perceived concerns of being "attached to a machine" and for those individuals with less complex insulin regimens. On a global scale it is likely that pens will ultimately be used by more people than artificial pancreas technologies.

Conclusion

New information from smart pens will transform diabetes care for the better, but education for health care professionals and training for insulin users will be required as to what to do with these new data. By harnessing the potential of artificial intelligence to identify patterns from insulin dose data for the purpose of decision support, we are at last on the verge of reducing the tremendous day-to-day burden faced by millions of people living with diabetes.

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Declaration of Conflicting Interests

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