

Medtronic automated insulin delivery device gets FDA nod

Dublin-based device maker Medtronic received US Food and Drug Administration (FDA) approval on September 28 to sell the first hybrid closed-loop automated insulin delivery device, the MiniMed 670G, for people with type 1 diabetes. The device integrates a continuous glucose monitor with a pump that automatically calibrates and delivers insulin to patients with type 1 diabetes. Clinical trials show that the device, which delivers basal or between-meals insulin as needed, increases the time patients were able to keep within their target blood sugar ranges.

The MiniMed 670G calculates how much insulin to infuse using a sensor that takes blood sugar readings every five minutes; it even shuts off insulin delivery when blood sugar levels fall. The system adapts to blood sugar changes during exercise and illness, and compensates for miscalculations of mealtime, or bolus, infusions, says Francine Kaufman, Medtronic's chief medical officer. "Whatever's going on, this device can automate the delivery of basal insulin," she says. Medtronic's results show that the MiniMed 670G kept people with type 1 diabetes within their target blood sugar range 72% of the time compared with 67% without the system. Overall glucose control improved, as shown by a drop in HbA1c levels, from 7.4% at baseline to 6.9% at the end of the study.

But despite headlines proclaiming MiniMed 670G as 'the first artificial pancreas', the system still requires patients to calculate mealtime infusions and inject the insulin boluses themselves. It also has no means of boosting blood sugar levels. Even so, the MiniMed 670G's ability to adjust basal insulin continuously is an advance over the previous automated insulin pump. This feature "is obviously what many patients and providers have wanted," says Yogish Kudva, a professor of internal medicine and endocrinology at the Mayo Clinic College of Medicine in Rochester, Minnesota.

Kudva, who has conducted trials with other Medtronic devices, says that although the FDA approval is exciting news, there are two issues to consider. One is how the insurance industry will deal with the device to make it accessible to patients. The other is how burdensome this device will prove to users, as current automated insulin delivery systems are difficult to use and too few patients are adopting them. Increased automation could help patients overcome their resistance to the technology, says Kudva.

The device's sensors are also more accurate than those in past devices, says Edward Damiano, a professor of biomedical engineering at Boston University. "Previous sensors really were inaccurate and very frustrating." He adds that the sensor in the MiniMed 670G is a significant improvement likely to translate



Medtronic's MiniMed 670G which automates basal insulin delivery for people with type 1 diabetes, is the closest yet to an artificial pancreas.

into the clinic. "This is a very positive step forward for people with type 1 diabetes."

Medtronic plans to deliver the MiniMed 670G in the US next spring and, pending other regulatory approvals, in Europe and elsewhere next summer, says Kaufman. Pricing will likely stay between \$6,000 and \$9,000, in line with currently available systems, according to a company spokesperson Kendra Cassillo.

Damiano is the founder and CEO of Beta Bionics, a startup developing a whole automated glycemic system. Much like the pancreas, the Beta Bionics device delivers the hormone glucagon, which increases blood glucose, as well as insulin, controlled by multiple algorithms, says Damiano. The company is a public benefit corporation that counts Eli Lilly among its funders. Beta Bionics aims to present the insulin delivery portion of its system for FDA review in the second half of 2018 and the full bi-hormonal system in the second half of 2019 or early 2020.

Other companies developing closed-loop insulin delivery algorithms include Bigfoot Biomedical of Milpitas, California, DreaMed Diabetes of Petach Tikva, Israel, and TypeZero Technologies of Charlottesville, Virginia.

Beyond the MiniMed 670G, Medtronic plans to further automate insulin delivery with a closed loop system that will incorporate an insulin-delivery algorithm licensed last year from DreaMed. "The goal ultimately is a device that automatically delivers all insulin with very little requirement from the patient other than wearing the device," says Kaufman.

Eric Smalley, Boston

Medtronic