

Scientists Getting Closer to Artificial Pancreas

Julie Steenhuysen

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CHICAGO (Reuters) Jun 24 - After more than three decades of development, researchers are coming closer to producing an artificial pancreas. But with lawmakers and diabetes advocates ramping up the pressure, U.S. officials this week outlined a regulatory path for a preliminary version of the device.

And while a seamless device that tracks blood sugar and automatically administers the right dose of insulin is still years away from commercial use, results of several studies being presented this week at the American Diabetes Association meeting in San Diego show real promise.

In one, researchers from Boston University and Massachusetts General Hospital tested a system using Abbott Laboratories' FreeStyle Navigator continuous glucose monitor and two insulin pumps made by Insulet Corp, all controlled by a laptop.

The system, which is designed to better mimic the body's natural mechanism of controlling both high and low blood sugar, was portable enough to allow adults with type 1 diabetes to roam around a hospital and use an exercise bike.

At the end of the 51-hour study, which involved daily exercise, two nights and six meals, six patients had an average blood glucose in the high 140s, equivalent to an A1c reading of about 7.

"It is very good. This is what we would call near normal blood glucose," said Dr. Steven Russell of Massachusetts General Hospital in Boston who is developing the system with Edward Damiano, a biomedical engineer at Boston University.

In another study, a team at Mayo Clinic hooked patients to accelerometers to track their movements and found that even moderate exercise plays a role in glucose. The team, led by Yogish Kudva, will incorporate this data into a sophisticated software program that acts as the "brain" of an artificial pancreas system, analyzing blood sugar and calculating when diabetics need a dose of insulin.

The team plans to start a clinical trial with the system this year or early next year, Kudva says.

So-called closed-loop systems -- in which a computer calculates a person's insulin dose and delivers insulin automatically through a pump -- are a far cry from the earliest version of an artificial pancreas developed in the late 1970s, says Dr. Aaron Kowalski of the Juvenile Diabetes Research Foundation or JDRF.

"It was the size of a refrigerator," said Dr. Kowalski, who oversees the group's Artificial Pancreas Project, a multimillion-dollar initiative aimed at accelerating progress toward a closed-loop automated insulin-delivery system.

With that device, patients were hooked up to an IV and could not leave their hospital bed.

The JDRF is working with Johnson & Johnson's Animas unit, which makes insulin pumps, and DexCom Inc, which makes continuous glucose monitoring devices.

Dr. Kowalski said nearly five years into the project, researchers are showing promising results, but he is frustrated with the pace of progress.

“People need better tools. Despite insulin pumps and continuous glucose monitors, there are still big challenges in diabetes management,” Dr. Kowalski said.

The group on Wednesday urged a Senate hearing to call on the FDA to stop delaying the study and approval of an artificial pancreas.

They cited a study published in the British Medical Journal that found that if an artificial pancreas were available, Medicare would save nearly \$2 billion over 25 years in costs related to diabetes complications.

The group is pushing to move beyond studies in academic settings and begin studies of the devices outside of the hospital setting.

“It’s great that we can do this in academic centers, and we’re learning a ton, but we need to get these projects to reach people with diabetes,” he said.

“We need to see these products commercialized. That is the big challenge, and that is why we are working with the FDA.”

Charles “Chip” Zimlik, chairman of the U.S. Food and Drug Administration’s Artificial Pancreas Critical Path Initiative, which was created in 2006 to accelerate the availability of an artificial pancreas system, says he is eager to have a system approved.

“The FDA wants the artificial pancreas on the market as much as anyone else does. We just have to operate within U.S. laws to make sure it is safe and effective,” Zimlik said.

Last week, the agency released guidance for how to develop a low glucose suspend system, an automatic shut-off mechanism used with an insulin pump. Medtronic already sells pumps with this the feature in Europe. It safeguards against a dangerous drop in glucose levels by temporarily halting insulin delivery.

By year-end, FDA plans to release detailed guidance on more complicated closed-loop systems, Zimlik said.

“We think of this system, the artificial pancreas, as one unit. There is going to have to be agreement among various companies to determine who is the reporting party for submitting it,” he said.

“That is a relatively new idea with respect to these systems.”

Zimlik, who is a type 1 diabetic, thinks the first approved devices will be ones that deliver insulin only, but he is very encouraged by the system being developed by the team at Boston University and Massachusetts General.

“They have what I call the Cadillac of closed-loop systems,” he said. In addition to delivering insulin, the device also delivers an infusion of glucagon.

“They are showing some very promising results,” he said.