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Insulin pump, glucose system is a significant step towards **artificial pancreas** technology

**BODY:**

The Juvenile Diabetes Research Foundation (JDRF) said that the federal government's approval of an insulin pump that also provides real-time, continuous glucose monitoring is a significant step on the path to the development of an **artificial pancreas**, with the potential to significantly improve diabetes care and lower the risk of complications.

JDRF, a charitable funder of research on type 1 diabetes and its complications, also praised the U.S. Food and Drug Administration's quick action in approving the device as critical to expediting the development of **artificial pancreas** technologies - a major research priority for JDRF.

The new device (the MiniMed Paradigm REAL-Time Insulin Pump and Continuous Glucose Monitoring System) was just approved by the Food and Drug Administration. It's the first integrated system for people with diabetes combining an insulin pump with a continuous glucose monitor.

"This represents another important step forward in diabetes treatment. By combining a sensor and a pump, people with diabetes will be able to take relatively immediate action to adjust their glucose levels," said Aaron Kowalski, PhD, director of Strategic Research Projects at JDRF. "Research clearly shows that the risks associated with diabetes complications are often directly tied to close control. With technological advancements, diabetes patients will be able to maintain healthier glucose levels and, as a result, prevent or delay devastating complications associated with diabetes."

He noted that JDRF is involved in a major program to fund research to illustrate the potential clinical (and, as a result, economic benefits) of continuous glucose monitors and closed-loop **artificial pancreas** systems.

According to Kowalski, research continues to show that current diabetes technology is inadequate. Some studies, he said, have found that even those patients who intensively manage their disease - measuring their glucose an average of nine times a day - spent less

than 30% of the day in normal glucose range.

The rest of the time, their glucose was either too high (which can lead to complications including eye, heart, kidney, and nerve disease), or too low (which can cause seizures, comas, and death). But studies have also found that patients with access to real-time glucose levels spent 26% more time in normal glucose range, and have statistically significant improvements in HbA1c levels, an important measure of longer-term glucose control.

"By improving the clinical outcomes of people with diabetes, and preventing serious and costly complications, technologies involving insulin pumps and continuous glucose monitoring have the potential to greatly benefit the U.S. healthcare system," explained Cynthia Rice, director of New Technology Access at JDRF.

She noted that total diabetes-related costs exceed \$132 billion a year, and that 32% of Medicare expenditures are spent on people with diabetes. Nearly 21 million Americans have diabetes, including some 3 million with type 1 diabetes, and one in three children will someday develop the disease. Diabetes is the leading cause of kidney failure and adult-onset blindness, increases the risk of heart attack deaths by two-to-four times, and leads to more than 80,000 amputations each year.

Insulin pumps enable diabetes patients to take insulin on both a pre-programmed and as-needed basis throughout the day and night. Continuous glucose sensors read blood sugar levels on a minute-by-minute basis using a small sensor that is inserted under the skin, which transmits data to a hand-held device. Some devices not only provide actual glucose readings, but can tell a patient whether their glucose level is trending upwards or downwards, allowing them to continually adjust their medication, diet and exercise to prevent high and low glucose levels.

Kowalski noted that, ultimately, a true **artificial pancreas** - or closed-loop glucose testing and insulin delivery system - will enable a person with diabetes to maintain normal glucose levels by providing the right amount of insulin at the right time, just as the pancreas does in non-diabetic individuals. Closed-loop technology will provide patients and their doctors with far more information about their daily glucose fluctuations and trends, and allow for far tighter control.

The **artificial pancreas** will test glucose approximately 1400 times a day (compared with a current average of two tests for the typical diabetes patient), and make insulin dosing information based on that real-time information. The system just approved by the FDA is an 'open-loop' system in which patients still make the decisions on insulin dosing based on sensor readings and a confirmatory fingerstick.

"The development of an **artificial pancreas** has been one of JDRF's top research goals, and we are cautiously optimistic about the potential benefit of new technologies," said Kowalski. "The technological future of diabetes care is coming much sooner than people had imagined, even just a few years ago."

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