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Researchers Eye Artificial Pancreas Device Considered Promising but a Decade Away

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Sept. 27, 2006 -- Engineers in the increasingly high-tech world of diabetes treatment are moving toward a quantum leap they hope will free some diabetes patients from the daily torment of finger pricks and insulin injections.

Several centers around the U.S. and in the United Kingdom are gearing up to test the feasibility of the first artificial pancreas to control patients' blood sugar.

Marketing of a self-contained artificial pancreas is probably a decade away, researchers say. But if this proves realistic, it could greatly improve blood sugar control for diabetics.

The artificial pancreas would not resemble a natural organ in the way an artificial heart approximates the shape of a human heart.

Instead, it would combine two existing technologies -- computerized blood glucose monitors and insulin pumps -- into a machine capable of sampling blood glucose, then delivering an appropriate insulin dose.

Type 1 diabetes affects approximately 2 million Americans. Only 44% of them achieve long-term control of their blood sugar with insulin, according to the National Institutes of Health.

Both the monitors and pumps have been credited with improving average blood sugar control in patients who use them.

What researchers don't know is whether they can "close the loop" between the two machines so they mimic a true pancreas.

Yale Study

Researchers at Yale University School of Medicine recently tested a prototype artificial pancreas under laboratory conditions and found the machine effectively controlled sugar levels in teenagers.

That study was small -- only 18 patients -- and limited to 36 hours in a hospital. That's hardly a real-world setting complete with varying diet, exercise, movement, and stress.

But, "Based on this, it's feasible," says Stuart Weinzimer, MD, a Yale pediatric endocrinologist who participated in the trial. He called the results "very, very preliminary."

Weinzimer and other researchers at Yale and other centers are starting a new series of trials to test artificial pancreas systems under a variety of conditions.

One protocol will test how well a "closed loop" functions when patients exercise or sleep, though the study will still be performed under hospital conditions.

"The long-term goal is for broad patient access and a thriving competitive market," Arnold Donald, president of the Juvenile Diabetes Research Foundation, told lawmakers at a Capitol Hill hearing Wednesday.

The group devoted $5.5 million to fund the new round of studies this year.

Work to Be Done

Mathematical algorithms that govern the link between blood sugar levels and insulin doses are yet to be perfected. Researchers are also working on backups that won't leave patients in danger if a sensor or pump fails.

After that, a manufacturer must show that the system is reliable enough in the real world to gain approval from the FDA.

Whether insurers will show an interest in paying for the device is another unknown.

"I really don't think it's going to be any sooner than 10 years," Weinzimer tells WebMD.

"It all comes down to 'are there enough fail-safes that if the hardware fails you're not walking around with no insulin without knowing it?'" he said.