JDRF Juvenile Diabetes Research Foundation International

dedicated to finding a cure

Fact Sheet

Accelerating Progress of the Artificial Pancreas: Bringing the Research Home

Type 1 diabetes is a difficult disease to live with—it must be managed 24 hours a day, seven days a week. It involves testing blood sugar levels and administering insulin multiple times a day. Despite advances in technology to help individuals live better and healthier, people with type 1 diabetes desperately need better tools to help relieve the burden of the disease and prevent its life-threatening complications.

In 2005, JDRF launched the Artificial Pancreas Project to speed the development of commercially-available, fully-automated systems to help people with diabetes maintain normal blood glucose levels. Since then, JDRF has made significant investments in research funding toward the Artificial Pancreas Project and has worked with others in the public and private sectors to advance the technology.

In fact, in 2009 the National Institutes of Health (NIH) funded multiple grants to help accelerate this process which are complementary to JDRF-funded research and funded through the Special Diabetes Program, a federal program established in 1997 by Congress to support type 1 diabetes research through the NIH.

A key step in the process of bringing the devices to market will be to test artificial pancreas systems in more "real world" conditions, and ultimately in a home setting, to ensure that the system is safe and effective at maintaining good control of blood sugar.

Studies show that tight control of blood glucose levels significantly reduces or delays the development of diabetic complications. Still, most patients with diabetes cannot achieve tight glucose control with traditional diabetes tools, spending only 30 percent of their days at healthy glucose levels. Blood glucose levels that are too high cause the devastating complications of diabetes, which can include kidney failure, blindness, nerve damage, amputations, heart attack, and stroke. Nighttime continues to be the most dangerous time of day for a person with diabetes. About 50-70 percent of hypoglycemic emergencies occur at night and can lead to dizziness, shakiness, seizures, coma, and in the worst case, death.

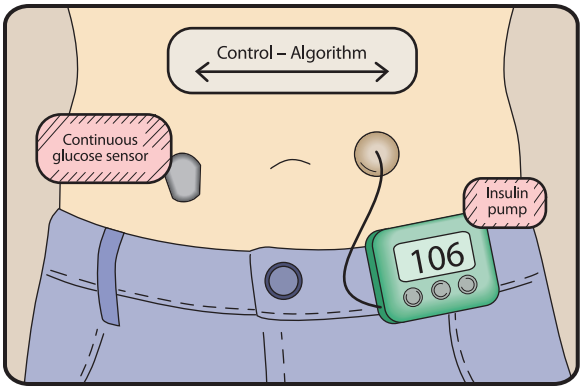
That's why JDRF is working to advance promising treatments and technologies like the artificial pancreas, to more effectively manage blood glucose levels in people with diabetes.

What is an artificial pancreas?

The artificial pancreas is an external device which people with type 1 diabetes could use to do what their bodies cannot—control both high and low blood sugar around the clock. It combines a continuous glucose monitor (CGM) and an insulin pump with sophisticated computer software to provide the right amount of insulin at the right time. Based on studies to date, JDRF expects first generation artificial pancreas systems to significantly improve

glucose control. JDRF's ultimate goal is a system that would replace as closely as possible what is lost when an individual develops diabetes.

It will enable people with diabetes to achieve tight blood glucose control and avoid both highs and dangerous lows, thereby significantly reducing the risk of the disease's devastating complications.



Who will benefit from an artificial pancreas?

The artificial pancreas will potentially benefit as many as 3 million Americans with type 1 diabetes, and would be transformational in the treatment of the disease. It may also have implications for those with advanced type 2 diabetes who are insulin-dependent. While the artificial pancreas is not a biological cure for diabetes, it will provide a better quality of life now for those suffering from the disease and help lower the risk of developing complications.

Where does the research stand now?

A growing body of evidence, based on JDRF-funded studies of artificial pancreas systems conducted in inpatient or hospital settings, demonstrates the potential of an automated system in improving and maintaining glucose control. Based on this data, a safe and effective system can, and should, be made with today's knowledge and technology, even as we continue to encourage the development of improved technology.

To prevent delays in the development of this transformational technology, the U.S. Food and Drug Administration (FDA) needs to provide clear and reasonable guidance so that outpatient artificial pancreas studies can proceed as soon as possible. This will provide researchers, the public, and industry a defined pathway toward the development of these systems.

What is JDRF doing?

It is important that research moves forward in a directed, accelerated, and effective a manner, with the patient in mind. JDRF has been working with researchers, industry, NIH and FDA to ensure that artificial pancreas studies advance safely and efficiently so that these devices can eventually reach individuals living with type 1 diabetes.

To help realize this goal, JDRF submitted a draft guidance to FDA, based on expert clinical recommendations. The document provides clinical testing guidelines for the development of artificial pancreas systems, and will serve as a roadmap for researchers and companies to develop safe and effective artificial pancreas devices.

JDRF is urging the FDA to adopt the guidance document because it will speed the development of safe and effective artificial pancreas systems to people with diabetes. Delayed approvals could mean adding years to the eventual delivery of an artificial pancreas.

For more information about the Artificial Pancreas Project, please visit JDRF at www.jdrf.org.

What are some relevant research studies to date?

A 2008 study by Dr. Stuart Weinzimer at the JDRF Hypoglycemia Center at Yale University tested a prototype closed loop system in five type 1 patients, ages 13-18, which suggested that a closed-loop system is feasible for use with children. Notably, nighttime control was dramatically improved and meal-time blood sugar rises were considerably lessened.

JDRF's landmark CGM trials published in 2008 and 2009 in *The New England Journal of Medicine* and *Diabetes Care* showed that patients with type 1 diabetes who used CGMs to help manage their disease experienced significant improvements in blood sugar control.

Published in *The Lancet*, JDRF-funded researchers at the University of Cambridge led by Roman Hovorka, Ph.D. showed that using a first-generation artificial pancreas system overnight in children and teenagers with type 1 diabetes can lower the risk of low blood sugar emergencies while sleeping, and simultaneously improved diabetes control. A subsequent study by Dr. Hovorka showed that adults with type 1 diabetes can use the artificial pancreas technology to significantly improve overnight blood glucose control without increasing the risk for hypoglycemia, across a range of real-life situations.

Science Translational Medicine published results from a clinical trial by Boston University's Edward Damiano, Ph.D., which demonstrated that patients were able to achieve near-normal blood sugar levels for more than 24 hours without hypoglycemia when using a bi-hormonal artificial pancreas device designed to more closely mimic the physiology of a person without diabetes. The device incorporated the use of glucagon, in addition to insulin, and demonstrated that glucagon consistently helped reverse the downward slope of blood glucose levels.

Bruce Buckingham, M.D. of Stanford University and Peter Chase, M.D. of University of Colorado have shown that over 84 percent of overnight hypoglycemic events could be avoided by using algorithms that predict impending hypoglycemia and switch off the pump for 90 minutes. This significant reduction in hypoglycemia was reported in their 2010 *Diabetes Care* paper and clinical trials are now in progress to study the effectiveness of these algorithms in an outpatient setting.