

## JDRF-Funded Clinical Trial Demonstrates Continuous Glucose Monitoring Improves Blood Sugar Control

A major clinical trial funded by the Juvenile Diabetes Research Foundation has found that people with type 1 diabetes who used continuous glucose monitoring (CGM) devices to help manage their disease experienced significant improvements in blood sugar control.

Results from the multicenter study were presented on September 8 during the European Association for the Study of Diabetes annual meeting in Rome, and portions of the data will be published in the October 2 issue of the *New England Journal of Medicine*, which is available online today.

The CGM study is a randomized, controlled trial involving 322 patients spanning the age range of 8 to 72 years. It took place at 10 academic, community, and managed care-based practices: the Atlanta Diabetes Associates, the Joslin Diabetes Center, Kaiser Permanente Southern California, Nemours Children's Clinic - Jacksonville, Florida, the Lucile Packard Children's Hospital at Stanford University, the Barbara Davis Center for Childhood Diabetes at the University of Colorado Denver, the University of Iowa, the University of Washington, and Yale University. The study was coordinated by the Jaeb Center for Health Research in Tampa, Florida.

Patients were assigned to use either CGM or to a control group using standard blood sugar monitoring, and were followed for 26 weeks to assess effects on blood sugar control, principally assessed by measurement of the HbA1c level. At enrollment into the study, patients had HbA1c levels of 7-to-10% (the goal for adults with type 1 diabetes generally is a level below 7% and for children and adolescents below 7.5-8%). Three age groups were analyzed separately: 8 to 14 years of age, 15 to 24 years of age, and 25 years of age or older.

Improvements in blood sugar control were greatest for CGM patients 25 years of age or older, whose HbA1c levels decreased (improved) during the study by an average of 0.53% compared with control patients. Improvements in secondary measurements were also significantly greater in CGM patients, including the percentage of patients able to achieve an HbA1c level below 7%, or a 10% relative or 0.5% absolute drop in HbA1c. The improvement in HbA1c occurred without an increase in hypoglycemia (low blood sugar), which is the worry when attempting to tighten glucose control.

In children from 8 to 14 years old, the average decrease in HbA1c was not significantly different in the CGM and control groups; however, those in the CGM group were more likely to lower their HbA1c by at least 10% and achieve HbA1c levels below 7% compared with the control group. Fifteen-to-24-year-old CGM patients, as a group, did not experience significant improvements in glucose control compared with the control group. CGM use varied with age, averaging at least six days a week over the course of the trial in 83% of the patients 25 years and older, but dropping off to 30% of the 15 to 24 year olds and 50% of the 8 to 14 year olds (for whom CGM use typically involved their parents' assistance).

Although the study was not specifically designed to assess the effect of frequency of CGM use on HbA1c, an analysis presented by JDRF and other investigators at the European Association for the Study of Diabetes meeting suggested that patients within all three age groups, including teens and young adults, who used the device at least six days a week had substantially lower HbA1c levels after six months compared with patients who used CGM less than six days a week.

"These results are very important, because they show that continuous glucose monitors are more than simply devices of convenience for people with diabetes -- they are tools that can substantially improve blood sugar control when used regularly," said Dr. Aaron Kowalski, Program Director for Metabolic Control at JDRF. "Based on the findings of previous studies, better control of glucose levels over the long term can be expected to translate to a lower risk of complications for people with type 1 diabetes." The lower levels of regular CGM use among children and teenagers observed in this study underscore the importance of continued research into a closed-loop artificial pancreas -- a device that uses CGM data to administer appropriate doses of insulin through a pump without the need for involvement of the patient or for young children their parents."

CGM devices, manufactured by several companies and approved by the FDA as an adjunctive therapeutic for diabetes, provide both a real-time snapshot of the glucose levels of a person with diabetes, as well as trend information on whether glucose is moving upwards or downwards, and how fast. Devices also provide warnings when the glucose is becoming too high or too low