

Study shows regular CGM use increases diabetes control for all age groups

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The latest data from groundbreaking human clinical trials of the effectiveness of continuous glucose monitors (CGM) show that the primary determinant of improvements in achieving better diabetes control is regular use of monitors - six days per week or more - rather than the age of patients, and that benefits continue well past the time when people with type 1 diabetes begin using the devices - including experiencing fewer low blood sugar emergencies.

The findings of two studies from the major multi-center trial funded by the Juvenile [Diabetes](#) Research Foundation were published online by the journal *Diabetes Care* (available at <http://care.diabetesjournals.org/papbyrecent.shtml>). The first showed that regular use of CGM devices is the principal factor in achieving better diabetes control, rather than the age of people using the monitors, or other demographic, clinical, or psychosocial factors. The second showed that people using CGM to help manage their disease were able to sustain good diabetes control; and just as important, that continued strong control came while actually lowering the incidence of hypoglycemia - dangerous low-blood-sugar incidents that can occur with tightly managed type 1 diabetes.

"Based on these results and previous JDRF CGM trials published over the past 12 months, we know that these devices can help people get in control of their diabetes, help people already managing their disease maintain good control, and help people stay in control over an extended period of time, while lowering their risk for hypoglycemia," said Dr.

William V. Tamborlane, of Yale University, a co-chair of the JDRF funded study.

Research has shown that good blood sugar control is a key factor in reducing the risk of the devastating long-term complications of the disease, such as blindness and [kidney disease](#) - but that the fear of low blood sugar emergencies often prevents many people from achieving tight control, and remains a constant concern for those who manage their diabetes well. The landmark Diabetes Control and Complications Trial (DCCT) showed that with intensive insulin therapy, excellent blood glucose control was obtained, but at the expense of a considerable increase in hypoglycemia. Today, the JDRF study has shown that, with CGM, hypoglycemia can be reduced while maintaining excellent blood sugar control over an extended period of time.

The JDRF CGM study was a randomized and controlled trial involving 451 adults and children ranging in age from 8 to 72-years-old at 10 sites, including the Atlanta Diabetes Associates, the Joslin Diabetes Center, Kaiser Permanente Southern California, Nemours Children's Clinic - Jacksonville, FL, 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, and coordinated by the Jaeb Center for Health Research in Tampa, Florida. 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.

People with diabetes try to maintain their blood sugar levels between 70 mg/dL and 180 mg/dL. When blood sugar becomes very low, people can become confused, lethargic, and even slip into a coma or die. Very high blood sugars can also be dangerous. And long-term, lack of control increases the risk of developing devastating complications, including eye, kidney, nerve, and heart disease. One measure of control is HbA1c,

which measures long-term blood sugar management; standards of good control are generally below 7% for adults, and below 7.5% to 8% for children, depending on age. Based on the DCCT findings, with respect to worsening of eye disease, a 10% decrease in HbA1c (7.2% vs. 8%) is associated with a 40% decrease in progression

According to one *Diabetes Care* paper (Factors Predictive of Use and of Benefit from CGM in [Type 1 Diabetes](#)), in the first six months of the JDRF trial, more frequent CGM use was associated with a greater reductions in HbA1c levels - a finding that was present in all age groups using the devices. Successful use of the devices was defined as an average of six days or more per week.

In each age group, patients averaging at least six days per week of CGM use had substantially greater improvements in HbA1c compared with those who used the devices less often.

According to the Jaeb Center's Dr. Roy W. Beck, the initial findings published from the JDRF CGM trials in the *New England Journal of Medicine* in October 2008, had noted that improvements in diabetes control for participants in the trial were most significant among those in the 25 and older age group; children, teenagers and young adults saw less dramatic improvements. However, he pointed out, the findings published in *Diabetes Care*, looking at those same trial results in a different way, show that after adjusting for the frequency of CGM use, the association of age group with improvements in HbA1c was no longer significant - in other words, participants in the trial in all age groups, from children through adults, who used CGM devices six days per week or more saw similar levels of improvement in their diabetes control. In addition, the study found that regular use of blood glucose testing prior to beginning CGM therapy was an excellent predictor of regular CGM use and thus of improvement in glucose control.

The second study published in *Diabetes Care* (Sustained Benefit of Continuous Glucose Monitoring on HbA1c, Glucose Profiles, and Hypoglycemia in Adults with Type 1 Diabetes) showed that CGM use had long-term impact: people who began the trial with HbA1c levels at 7% or above saw a reduction in HbA1c mainly in the first eight weeks of the study, and then remained relatively stable through the next 44 weeks; and for participants who began the trials with an HbA1c below 7%, they remained within that target range over the entire 12 months of the study.

"In this six-month extension to the trial, we found that most adults continued to use CGM almost every day, and had sustained benefits in diabetes control as measured by HbA1c levels and the amount of time blood sugar was in the target range," said Dr. Aaron Kowalski, Program Director for Metabolic Control at JDRF. "These benefits persisted despite less intensive follow-up over the second half of the trial than the first, which was designed to approximate usual clinical practice."

He noted that just as important as the persistence of control that CGM devices helped patients achieve was the remarkably low rate of severe hypoglycemic events during the second six months of the study. Severe hypoglycemic events - which required the assistance of another person or medical professional - were experienced by 10% of the study participants during the first six months of the trial, but only by 4% in the second six months. The rate of severe hypoglycemic events fell from 21.8 events per 100 person-years during the first six months to 7.1 events per 100 person-years during the second six months. The rate was not associated with the HbA1c level of the trial participants at the time the study began.

According to Dr. Tamborlane, an investigator in both the JDRF CGM Trial and DCCT trials, the rate of severe hypoglycemia in people using CGM devices during the second six months of the JDRF trial was markedly lower than in the Diabetes Control and Complications Trial

intensive treatment group - seven hypoglycemia events compared with 62 in the DCCT trial - even though the mean HbA1c of JDRF trial participants at 6.8% was lower than the DCCT trial participants' level of 7.1%.

"Plus, the total absence of severe hypoglycemia during the second six months of the study in the participants who began the trial with an HbA1c below 7% is particularly striking, especially since these subjects were able to maintain a mean HbA1c of 6.4%," Dr. Tamborlane said.

These studies are the third and fourth publications resulting from JDRF's groundbreaking CGM trials, established to clinically assess the benefits of CGM devices in helping people with type 1 diabetes manage their disease more effectively. In addition to results published last fall in *The New England Journal of Medicine*, results were published in May in *Diabetes Care*, showing that people with type 1 diabetes who have already been successful in achieving recommended [blood sugar](#) goals (below 7%) can further benefit from using continuous glucose monitoring (CGM) devices, while experiencing less [hypoglycemia](#).

JDRF has actively shared the results of the CGM trial with health insurance plans, and as a result many of the nation's leading plans including Aetna, Cigna, Kaiser Permanente, United Healthcare, and Wellpoint now cover CGM for patients with type 1 diabetes. In addition, due to the JDRF trial, CGM is now included in national standards of care for type 1 diabetes, making doctors more likely to prescribe them for patients.

Source: Juvenile Diabetes Research Foundation International ([news](#) : [web](#))

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