

### Charlotte Cunningham

#### *With Type 1 Diabetes, “Time Is of the Essence”*



**Charlotte Cunningham**

Late in the summer of 2005, Lilo Cunningham noticed that her then 10-year-old daughter, Charlotte, was beginning to drink copious amounts of water. This seemed unusual to Lilo because Charlotte was not fond of drinking water. “But no matter where we went, she was always looking for a water fountain,” says Lilo. Lilo also noticed that Charlotte was using the bathroom more frequently.

Lilo recognized these changes in Charlotte’s behavior as potential symptoms of diabetes. As two of Lilo’s sisters have sons with the type 1 form of the disease, Lilo decided not to take a chance. Within days of her observations, Lilo made an appointment with Charlotte’s pediatrician and, sure enough, learned that Charlotte’s blood sugar level was 680—about seven times above normal.

Charlotte was diagnosed with type 1 diabetes—previously known as juvenile diabetes—a devastating illness that often strikes in infancy, childhood, or young adulthood.

The diagnosis was frightening, but Lilo was able to turn to her sisters for advice. In addition to offering

many practical suggestions for dealing with diabetes on a day-to-day basis, one of Lilo’s sisters, who is very active in the Juvenile Diabetes Research Foundation International (JDRF), informed her that several diabetes research trials were under way. She suggested that the Cunninghams might want to investigate these trials for Charlotte.

Because the Cunninghams were informed of several clinical trials shortly after Charlotte’s diagnosis, she was eligible to participate in a clinical trial specifically designed for newly-diagnosed patients. The therapy being tested in this trial may slow down the progression of the disease, which could reap long-term benefits for patients and make it easier for them to control their blood sugar levels.

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Controlling blood sugar levels is critical. The NIDDK’s landmark Diabetes Control and Complications Trial (DCCT) demonstrated that intensive blood sugar control offers remarkable long-term benefits when it comes to preventing or delaying complications frequently associated with type 1 diabetes, including eye, nerve, kidney, and cardiovascular disease.

Charlotte, now 13 years old and 3½ years post-diagnosis, shows no signs of complications from diabetes. “Time is of the essence,” says Lilo. “The more we can slow the progression of this disease and keep Charlotte healthy, the better chance she has of leading a longer, healthier life.”

## PATIENT PROFILE

### About the Study

Type 1 diabetes occurs when a person's immune system mounts a misguided attack and destroys the insulin-producing beta cells found in the pancreas. Insulin is critical for the body to absorb sugar from the blood and to use it for energy. Those with type 1 diabetes need daily administration of externally-supplied insulin, either by injection or with a pump, and must monitor their blood sugar levels vigilantly. Researchers have discovered, however, that many individuals diagnosed with type 1 diabetes still make detectable amounts of insulin, even many years after they are diagnosed. The DCCT also showed that people with type 1 diabetes who still made some of their own insulin had fewer long-term disease complications, as well as reduced incidents of dangerously low blood sugar (hypoglycemia) from administration of too much insulin. These observations suggest that preserving patients' remaining beta cell function, so that they still produce some of their own insulin, could have dramatic, long-term health benefits.

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The trial in which Charlotte is participating is trying to do just that. A previous NIDDK-supported clinical trial indicated that an antibody, called hOKT3gamma1(Ala-ala) or "anti-CD3," halted the destruction of insulin-producing beta cells in a small number of newly-diagnosed patients. Anti-CD3 alters the signal that triggers the disease-causing immune cells to attack the insulin-secreting cells. Charlotte is participating in a trial where researchers are determining if an additional treatment of anti-CD3 will provide further benefit, beyond that of the single treatment. This trial is being conducted by the Immune Tolerance Network,

which is led by the National Institute of Allergy and Infectious Diseases, in collaboration with the NIDDK's Type 1 Diabetes TrialNet. Both networks also receive funding from the Special Statutory Funding Program for Type 1 Diabetes Research. Because one of the requirements for participation in this particular trial was that patients enroll within 8 weeks of their diagnosis, the Cunninghams are very grateful that a family member counseled them to act quickly after Charlotte's diagnosis.

"We were fortunate that Charlotte was diagnosed so early and was able to participate in this trial," says Lilo. "As a result, she's perhaps making more insulin than the average person in the early stages of diabetes and is doing very well."

The trial requires Charlotte to be infused daily over a 14-day period with the anti-CD3 antibody. Each daily infusion takes between 15 to 30 minutes, and is administered into Charlotte's upper arm. Charlotte received this 14-day set of infusions two times; the second treatment followed 19 months after the first. Charlotte returned to the trial site every 3 months in between the treatments and for 12 months following the second treatment. These visits were to monitor her response to the treatment and included a physical examination, a blood test, and a test to measure her insulin response. Except for a rash between her fingers, which lasted only 1 day, Charlotte has experienced no side effects from the treatment.

When asked about her overall experience in the trial study, Charlotte responded, "It was very cool." Not the typical response one would expect from an adolescent, but Charlotte has handled her diabetes extremely well from the beginning.

### **Lilo and Charlotte's Message: Don't hesitate. Act quickly.**

When it comes to diabetes, Lilo and Charlotte's message to others is clear and simple: At the first sign of symptoms, do not hesitate; act quickly.

## PATIENT PROFILE

“If you have any suspicions or notice anything wrong with your child, go for a blood test [at your pediatrician’s office] and follow up immediately,” says Lilo. “If this study succeeds in allowing Charlotte to retain the ability to produce some of her own insulin, even for a little while longer than she might have otherwise, it will help to delay, reduce, and possibly even prevent the secondary complications that often accompany type 1 diabetes.” “And make sure you check your blood sugar level regularly,” adds Charlotte.

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Lilo has not observed symptoms in other family members, but that does not mean she was going to take chances. The Cunninghams enrolled their two other children, Charlotte’s 16-year-old brother and 19-year-old sister, in a study as well—the TrialNet Natural History Study. This study is screening relatives of people with type 1 diabetes to determine what level of risk these family members have for developing the disease. These studies are being conducted to learn more about the causes and indicators of risk for the development of type 1 diabetes. So far neither one of Charlotte’s siblings appears to be at increased risk. “But if either of them should show signs of the disease, I would enroll them in a clinical trial in a heartbeat,” Lilo says. “We had an incredibly positive experience with Charlotte’s study. We were exposed to so many people who know so much about this disease—we learned so much!” When asked her thoughts on participating in the trial, Charlotte proudly says, “I’m an example of how diabetes research is helping people.”

### About Charlotte

Since February 2008, Charlotte’s need for injected insulin has increased dramatically. According to Lilo, it is hard to say exactly what is going on. “Charlotte is in the midst of puberty, which could mean her body is requiring more insulin because of hormonal changes,” she says. Nineteen months after her first treatment, Charlotte received her second and final 14-day infusion as part of the trial. The good news is that, even though Charlotte needs more external insulin, tests performed in May 2008 (12 months after Charlotte’s last treatment and nearly 3 years after her initial diagnosis) indicate that she is still producing some insulin. Because her need for external insulin is increasing, Charlotte is exploring the possibility of using an insulin pump, a portable device that injects insulin at programmed intervals. She says she is excited about the prospect of using the pump.

If anything, Charlotte’s life has become more active, rather than less, since being diagnosed with diabetes. Prior to her diagnosis, Charlotte played tennis and basketball. Now she has added surf boarding, lacrosse, and softball to her repertoire of physical activities. “Having diabetes hasn’t really affected me much when I’m doing sports,” she says. “I need to make sure my blood sugar count is okay both before and while I’m playing, but my coaches are very understanding and let me do what I need to do to take care of myself.”

In the meantime, at the time this story was written, Charlotte was preparing to go to summer camp with 70 of her peers, all of whom have diabetes. She has been to the camp twice before and says she likes it a lot. “We meet with meal planners and check our blood sugar regularly, but mostly it’s a regular, fun camp,” Charlotte explained. Like any 13-year-old, Charlotte simply wants to lead as active and normal a life as possible.