

HEALTH

Revolutionizing How Type 1 Diabetes Is Treated



Thirteen-year-old Louis Cocco one day hopes to become a professional hockey player, but at age two he was diagnosed with Type 1 diabetes, which could stop him from achieving his goals. Four years ago his endocrinologist, Dr. Claresa Levetan, promised him that he will be off insulin by the time he is an adult, and she intends to keep her word so he can reach for the Stanley Cup.

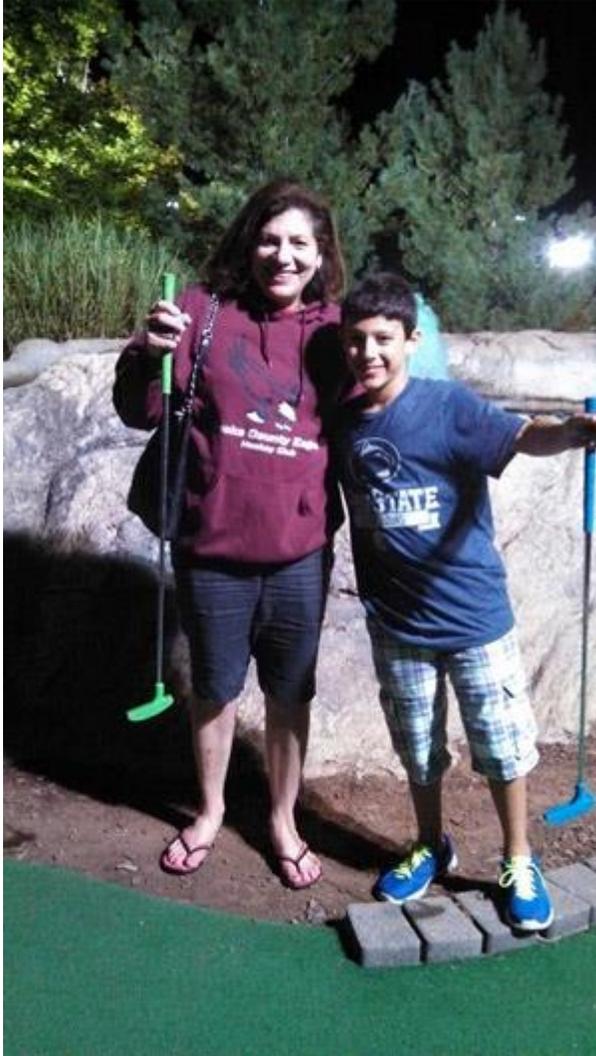
His blood sugar is checked 15-20 times a day and he now requires 8-10 insulin shots a day—but all of that is about to change. Levetan’s groundbreaking research could lead to a cure for Type 1. “I see a healthy, young vibrant kid with a future packed with dreams,” explained his doctor, “and behind that is a pretty tough life for him and his family.”

At seven years old, Cocco was asked, “What would life be like without diabetes?” “It would be

like walking on a cloud,” he said, as he moved his hand in a straight line to indicate no bumps.

“My life is kind of bumpy now— yeah, just like my sugar.”

That's why Levetan's team has worked tirelessly for Cocco, just so he can be like everyone else. "We work for you," said his doctor. "You are the boss." The boy beamed, "She is one heck of a lady!" he told his mom.



She is inspired by all her patients like Cocco, who just want to be a kids-without the needles and highs and lows, sugar crashes, and late night drama. "I am pretty excited to wake up every morning because I get to do the work that I love to do and that I feel has to be done," explained Levetan. "There is nothing that is going to stop us from getting Louis off insulin."

At an early age, Levetan witnessed the ravages of Type 1 first hand when a close family friend's health declined rapidly after her diagnosis. "I got to see a women who was vibrant and healthy deteriorate over a period of 10 years, lose a limb, lose her vision, and go on dialysis and pass away. That left a big impression on me," recalled Levetan.

"This is a horrible disease. The swings from low to high blood sugar make diabetes the leading cause of blindness, amputation, and kidney

failure," explained Levetan. That tragedy has driven her to become an endocrinologist on a 30-year quest to change the way Type 1 is treated.

She and other pioneers in the field, like auto-immune disease expert Dr. Eli Lewis, who is the director of the Clinical Islet Lab at Ben-Gurion University, are radically changing how Type 1 is being approached.

"My lab is dedicated to finding something closer to a cure—no more syringes of insulin—our goal is a pancreas that produces enough insulin," said Lewis.

Why the urgency? Each year in the United States 15,000 children are diagnosed with Type 1, about 80 people per day. Three million people live with these challenges daily—a sobering statistic. Once known as juvenile diabetes or insulin-dependent diabetes, Type 1 is also diagnosed in adults. It is a chronic condition in which the pancreas produces little or no insulin, the only hormone that moves sugar (glucose) into fat and muscle cells for energy, and away from the blood circulation. During digestion, the liver produces glucose from the foods that people eat, the body's main source of fuel and energy. When excess glucose builds up in the blood, this can cause long-standing damage and serious health issues.

Levetan's accomplishments in diabetes research have inspired her to establish Perle Bioscience, Inc. Her team just patented a combination therapy for Type 1.

"We have developed a therapy that generates new insulin-producing cells from the stem cells already in the pancreas," theorized Levetan, Chief of Endocrinology at Chestnut Hill Hospital in Philadelphia and Founder of Perle Bioscience, Inc. "We came to the conclusion that to have insulin independence, you will need both a regeneration agent and an immune agent to protect those new cells."

In the next several months, Levetan's first human clinical trials will begin for newly diagnosed cases then will proceed to existing patients. Patients will be given doses from two FDA-approved oral drugs.

Meanwhile, at Ben-Gurion University of the Negev in Israel, Lewis is excited about the results from his collaborator's three major clinical trials in the United States and Israel using an FDA-approved Alpha 1 infusion drip, a blood protein that the body naturally produces when people are sick. Alpha 1 has been used to treat emphysema, a rare lung condition, and Lewis hopes to extend this highly safe approach to other auto-immune conditions.

"Participants stopped night time insulin injections—a time when manual insulin use is most dangerous. Some haven't needed insulin injections for more than two years," Lewis reported. Furthermore, he said that because of the positive results a new phase of clinical trials to determine proper dosing is now underway in all three centers.

This profound discovery holds the key to ending insulin injections forever and perhaps curing diabetes," explained Lewis." The key is to interfere with early cellular injury within the pancreas

in a safe manner. The immune system perceives these changes as signals for protection rather than destruction.”

Levetan’s clinical trials will be open for patient recruitment in the fall of 2014 and will be open to patients with new onset (within 6-months) Type 1 diabetes. Also, since Lewis’ approach is an existing FDA-approved drug, his off-label Alpha 1 treatment is available under a physician’s prescription, too—like a San Antonio mom did for her recently diagnosed son.

Dana Green was devastated after Zach’s diagnosis. Shocked, she said, “That does not run in my family.” Once Green recovered from the blow, she explored recent studies and discovered Lewis’ groundbreaking research and safe clinical trials.

“I came across Dr. Eli Lewis’ work, read all the articles, and researched all the clinical trials,” explained Green. “The most important thing was that it was safe and there were no side effects.”

This prompted Green to contact Lewis. She found a local physician who prescribed the Alpha 1 treatment and a blood infusion center to treat Zach for the weekly visits of slow-drip infusions. Already after two weeks of treatment, Zach was producing more insulin on his own. After a couple of months, he was taking virtually no injections. This has had a huge impact on the entire family.



Green later came upon Levetan’s promising work. In fact, it was Green’s resourcefulness that connected these research teams, and soon Lewis and Levetan may be collaborating, developing a broader umbrella of protection for a wider range of patients with Type 1 diabetes.

These enthusiastic global research teams believe that they will revolutionize the way autoimmune diseases are treated and make insulin needles obsolete. This means that Cocco won’t have to put his aspirations on hold, and kids, like this rambunctious thirteen-year-old, won’t have to wait to reach for their life-long dreams.



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