



Leading Endocrinologists, Researchers Herald Current Regimens And New Technologies in Path to Artificial Pancreas

ChildrenWithDiabetes.com Roundtable Panel Taps Harvard, Stanford, NIH, JDRF and Industry Experts

Amid a rising epidemic, people with diabetes need better access to and awareness of the impressive array of control strategies available today, as well as near-term developments that promise even better patient outcomes, according to a distinguished panel of experts led by ChildrenWithDiabetes.com (CWD), an independent consumer resource. While panelists felt an outright cure is at best "hoped for" within our lifetimes, the doctors and researchers from Harvard, Stanford, the National Institutes of Health, the Juvenile Diabetes Research Association and private industry concurred that new technology and science now underway promise to make significant advances over the next several years, including next-generation continuous glucose sensors, "closed-loop" artificial pancreas systems to replicate the body's management of blood sugar, and refinements to improve islet cell and pancreas transplant techniques.

The lively discussion, led by Dr. Helena Rodbard, a pediatric endocrinologist and past president of the American Association of Clinical Endocrinologists, and co-moderator Laura Billetdeaux, a CWD director and the panel's consumer voice, included these topics:

- solutions and strategies in use today that prevent diabetes' harmful effects, why people don't use them, and how to remove those roadblocks
- research in areas that could provide significant improvements in 3-10 years such as automatic, continuous glucose measurement, an artificial pancreas, and islet cell transplant
- and the far-off hope for a cure.

Techniques, Technology Dramatically Improve Outcomes

The prognosis for the 17 million Americans with diabetes and the 1 million added each year is excellent if they maintain their treatment and control, according to Dr. Rodbard. And that control is much easier compared to predominant regimens in use up until a few years ago such as boiling

syringes, sharpening needles, urine tests and painful, relatively large finger sticks. "The very first home glucometer wasn't on the market until 1981," she said in recalling her grandmother's struggle with the disease.

For Billetdeaux, life changed with her son's diagnosis of diabetes at age 8, but today "he is alive and healthy and wonderfully so... a hockey player, straight-A student and the class President...and the reason he is all those things is because of the technology that we have."

Children and adults diagnosed with pre-diabetes or with Type I or Type II diabetes can have significantly longer, healthier lives than people did just 10 or 20 years ago.

"The current therapies with self-monitoring and the [insulin] delivery devices, and the improved preparations of insulin, have already made a huge difference, and every incremental improvement that we make is absolutely worth it as we get to the cure," said Dr. Judy Fradkin, adult endocrinologist and Director of the diabetes division of the National Institute of Diabetes and Digestive and Kidney Diseases for the National Institutes of Health.

Continuous Monitors: Key Step to Artificial Pancreas

"From a parent's perspective," said Billetdeaux, "I think if you polled a thousand families, they would say that an artificial pancreas is pretty darned close to a cure in our eyes."

A closed-loop, artificial pancreas would involve an integrated, largely automatic combination of a continuous glucose meter that would activate release of insulin via an insulin pump.

"The pumping technologies are in pretty good shape. It's a matter of having a sensor that has the ability to provide real-time results and allow people to manage their disease permanently," said Tim Goodnow, Vice President of R&D for Therasense, which makes the Freestyle blood glucose monitoring system and is developing a continuous sensor providing patients real-time, routine monitoring, now in FDA trials. "The thought of going directly to a closed loop [artificial pancreas] is fairly intimidating, but I think we will see the development of incremental steps in that direction over time."

"Continuous glucose sensing is opening up a lot to us in terms of seeing much more of what's going on and the concept of beginning to integrate it eventually with insulin infusion is going to be very, very powerful," said Dr. Bruce Buckingham, pediatric endocrinologist at Stanford University's Packard Children's Hospital.

Many challenges will need to be overcome, in the product design, ease of use for patients, and the biology.

Several continuous monitors and sensors are in development by the medical industry, and several of the panelists are involved with early trials on systems that take differing approaches including sensors that take readings above the skin, just below the skin, and potentially also from within the body.

New Technology Has to be Easy, And Keep Patients in Control

Patient ease-of-use will be key, said Dr. Alan Moses, endocrinologist and Chief Medical Officer at Joslin Diabetes Center in Boston. He's also a Professor of Medicine at Harvard and father of a young adult who grew up with diabetes.

"With some of these downloads [from the study trials], it [can be] just a jumble of lines and data points," he said. "You need to have some way of putting that into a recommendation...so that when you download to a device, it will say that over the last two days, it looks like you're running high after a meal, or you're in danger of being low at night."

Dr. Buckingham, also involved in study trials, said the interest in these technologies is very high, and "families really come flocking in -- everyone wants to sleep at night," he said.

Mom Hears the Alarm, Dad Sleeps Through It

One study illustrated the value of overnight monitoring - and the humorous but important differences in human interaction with technology.

"When we put [the continuous monitors] at a diabetes camp, the female counselors complained because they were wakened all night and the male counselors didn't hear the alarm go off," said Dr. Buckingham, with a laugh. "The typical male/female difference."

Other variables need to be researched as well, including better understanding of the body's internal chemistry - insulin and other pancreatic hormones, glucose interaction, and the variables of outside factors such as carbohydrate intake.

"When you look at controlling anything, in this case blood glucose levels, an automatic system has to also recognize that those other changes are present and potentially take action," said Rhall Pope, PhD., Vice President of Research and Development at Deltec, a maker of ambulatory infusion devices including insulin pumps. "The algorithms that go in have to have the intelligence to do that."

Islet Cell Transplants on the Horizon

Islet cell transplant is another emerging treatment, but also years away.

New study results discussed at recent transplantation meetings in Washington showed substantial proportions of patients who now are able to become insulin free after pancreas transplantation, but there are significant other hurdles, from the glucose biochemistry to side effects of immunosuppressant drugs, according to NIH's Dr. Fradkin.

"You have to have very severe diabetes to make [islet transplant] worthwhile," she said. "Many of them actually don't have completely normal glucose tolerance to begin with, and second of all, the drugs that are used are certainly not without toxicity. Many or most of the patients have diarrhea, have mouth ulcers, have all sorts of symptoms from the treatment."

"Insofar as children are concerned, [islet transplant] is even further away, because it's going to be done in adults for a long time to establish the safety of the procedure," added Dr. Richard Furlanetto, a pediatric endocrinologist and currently Scientific Director of the nonprofit Juvenile Diabetes Research Foundation.

Patients, Parents Are The Best Medicine

People with diabetes, and their families, have to educate themselves, not only for good daily control and care but also to stay on top of new developments, said Billetdeaux.

"I'll give you an example," she said. "Sam was routinely, for a year, running in the 300 range and taking 90 units of insulin a day and we could not get him under 300. It was just awful and he felt awful. We read an abstract online about Metformin use in teens. I went to our clinic and I said, may we try this? Our endocrinologist said, we've never done that before. And I said yes, but somebody has, because here is the abstract. They were very good there with us. Sam tried it and within a month, he was using 50 to 60 units of insulin a day, his A1C was down to 6.8 and he's 85 percent in range.

Billetdeux challenged patients and family members to keep a strong relationship with their doctor, Diabetes Educator or health-care provider, and to be active readers and consumers of information. ChildrenWithDiabetes.com, founded 8 years ago by Jeff Hitchcock after his child was diagnosed with diabetes, has over 18,000 web pages of content, but there are many, many resources, she said.

"There are so many great online organizations, JDRF, American Diabetes Association, lots of others," she said. "Just get online with someone and start reading."

Innovative Programs at Home, at School

One new program centered at Joslin, called Telemedicine, is bringing health care to people who might be in more isolated areas, said Dr. Moses. At very low costs, patients utilize a TV-top box, their TV, and phone lines to send their health information to a doctor, and then receive advice and information that displays on their TV.

The NIH also launched in June a comprehensive school guide - a printed manual, and website-based resource - for school administrators, teachers and other staff to access information about diabetes, emergency care recommendations, school program and education ideas and the like, said Dr. Fradkin.

Use Today's Proven Tools. . .Don't Wait for Tomorrow

While the future is bright for new developments, good glycemic control has to be a "here-and-now" constant routine, several panelists intoned. As Laura Billetdeux said after the roundtable: "The best cutting-edge products and techniques are those on the market today, extending and improving life for people with diabetes everyday."

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