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## Avoiding the ups and downs of diabetes

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As she waited in the Denver airport for an April 4 flight to Nebraska, Karen Koch felt a little dizzy.



The DexCom STS continuous glucose monitor displays a chart of blood sugar readings for the previous nine hours and sounds alerts when readings go outside the

A type 1 diabetic for more than four decades, Koch assumed her blood sugar was a little low. But the Kearney, Neb., woman - a nurse who travels through Nebraska and Kansas showing diabetics how to use their insulin pumps - couldn't immediately find her glucose meter.

So she bought herself a soda, which usually did the trick.

But even after a few sips, she dropped to the floor.

Koch awoke with a concussion, the first tinges of a nasty black eye, and the sense that she was in heaven. A gaggle of handsome male paramedics surrounded her, offering her a Pepsi and an ambulance ride.

Two days later, back on earth, Koch got herself a continuous glucose monitor.

The pagerlike hunk of plastic tucks in her pocket or purse or rests on her car's dashboard. It comes with a disposable sensor she sticks into her abdomen and a tiny wireless transmitter that clips to the sensor. The receiver's display shows her blood sugar level every five minutes and, more importantly, where it has headed for the past nine hours.



Karen Koch

Koch programs the monitor to alert her when her levels are outside the target or nearing high or low danger zones.

It wakes her at night when her blood sugar dips - vibrating against her wooden nightstand and making an increasingly loud and piercing "Beep! Beep!" akin to that of a backing-up truck.

And it sounds a different pitch when it senses her sugar is too high - a signal that she might need to take more insulin after a confirmatory finger-stick.

This expensive little device, the DexCom STS, is one of three continuous glucose monitors the Food and Drug Administration approved this year for ongoing home use by adult diabetics with a prescription. (The two others are made by Medtronic.) A fourth, the Abbott Navigator, is under FDA review. And dozens of biomedical companies are working to develop and refine other continuous glucose monitors.

The devices haven't been widely studied, aren't accurate enough to replace finger-stick blood sugar tests and aren't yet approved for those younger than 18. And the devices are neither routinely covered by insurance nor widely prescribed by doctors.

But as the machines' accuracy and affordability improves, they hold significant potential for patients with both type 1 and type 2 diabetes.

Knowing one's blood sugar levels over time is key to managing diabetes - and difficult to do with finger-sticks alone.

Research shows that diabetics who reduce their average blood sugar levels also reduce or eliminate the harmful consequences of diabetes. Those include the sudden dizziness that causes accidents, falls and ambulance rides, like Koch's in Denver, as well as the more slowly evolving problems - blood vessel disorders, strokes and heart attacks, kidney and liver disease, foot and eye problems - that are hospitalizing, harming and killing diabetics in America every day.

Dr. James Lane, endocrinologist at the University of Nebraska Medical Center and president of the leadership council for the local American Diabetes Association, said eliminating or reducing wild swings in blood sugar, not just lowering average blood sugar, also may play a significant role in reducing diabetic complications.

Initial evidence suggests the monitors help with both.

A review published last year in the journal *Diabetes Care* said five randomized, controlled studies found that patients who used continuous glucose monitors improved their HbA1c levels - a measure of blood glucose elevation over time and an indicator of serious diabetes complications in the future.

Small, industry-funded studies show that, even without any coaching on when or how to react to the readings, patients had fewer wild glucose swings within a week of using the monitor.

Koch said she got her monitor for about \$450 on an introductory special, though it has a list price of \$800. She pays \$35 for every three-day sensor, making a month's supply about \$350. Insurance doesn't cover any of those costs. But she points to an HbA1c level that's dropped a full point since her scare this spring and her \$6,000 Denver ambulance bill as evidence it's worth it.

"I think it's saved me at least a dozen times from a low blood sugar - and many high blood sugars, too," she said. "If insurance companies would look at this a little bit, they'd see that it's cost-effective."

Dr. Aaron Kowalski, a national advocate with the Juvenile Diabetes Research Foundation who wears a DexCom device to help manage his own diabetes, said he expects the FDA to extend approval of the latest monitors to children in the coming year. He predicted that continuous glucose monitors eventually will couple with insulin pumps and sophisticated software to function as an artificial pancreas for those who depend on externally supplied insulin.

Kowalski said that's why the foundation is pouring millions into research on the monitors' effectiveness and future refinements.

Kowalski said the devices have improved in the past few years, with those on the market now above 94 percent and 96 percent accuracy. Nonetheless, he said, the devices require calibration at least twice daily with a finger-stick blood test. And users are instructed to use finger-stick blood draws to confirm readings before acting on them.

"The only thing worse than no information is bad information," cautioned Lane, who said he reserves concern about the devices' accuracy.

Koch said that in eight months of use, though, she's come to rely more on the trend data than individual readings.

"For me, there have been times when it was totally off and the little probe might have been bent or something," she said. "But there have been more times that it's dead-on. You have to be realistic and not expect perfection yet. But it's getting there."

Additionally, the monitors help patients work on control with their doctors.

Koch, for example, downloads weekly information from her monitor, prints it on her computer and forwards it to her endocrinologist. The doctor then makes insulin dosing suggestions. Notes handwritten on a recent printout suggest: "increase basal dose 0.1" at a high point early in the morning and "decrease basal 0.1" at a low spot in the afternoon.

Even short-term use of the monitors can help doctors and patients get a better read on the daily blood sugar roller coaster.

Mark Baumann, 49-year-old Omahan with type 1, checked out a temporary glucose monitor - an older model that didn't show him his readings until a download at the end - from his doctor for three days in January.

The biggest surprise? "My body did not consistently react in the same way to the same activity or the same food two days in a row," he said.

Knowing that, he said, he'd like to get one of the new monitors - even if he'd still have to prick his fingers to confirm the readings.

"It's like driving a car," he said. "If you didn't have a speedometer, you'd just be relying on yourself. If the speedometer only flashed at you six or seven times a day, you'd have to guess an awful lot. But if I had something that gave me this constant update, I could probably manage my speed better."

The cost, though, is prohibitive.

"A thousand dollars would not keep me from considering the use," said Baumann, a project manager with Microfilm Imaging Systems. "Five thousand dollars a year, though, I'd probably have to think about it a lot harder."

Dr. Chuck Tomek, a Lincoln physician and Omaha parent whose 13-year-old daughter has type 1 diabetes, weighed the benefits and cost of the new technology at a recent Juvenile Diabetes Research Foundation breakfast.

He said he hadn't realized the monitors could have such a significant impact on HbA1c levels and, thus, life-threatening complications.

"Three to four thousand a year," he said, calculating a 12-month sensor supply. "To extend her life, that's worth it."

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