Are all home-based blood sugar tests equal?

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FDA takes steps to eliminate potential risks for people with diabetes.

(HealthDay)—Every day, millions of people with diabetes—both type 1 and type 2—rely on the results they get from their blood glucose meters to guide their treatment decisions. But, what if those test results were wrong?

Recent research has found that even though a blood glucose monitor meets the U.S. Food and Drug Administration's standards for accuracy to gain device approval, the meter or test strips used in the meter may not perform as well as expected in the real world. And, those errors can have potentially life-threatening consequences.

"The availability of accurate blood glucose meters and test strips is critical to the success of diabetes self-management," according to a statement from the American Diabetes Association. "Faulty or

inaccurate equipment can not only lead to just poor diabetes self-management, but to an acute medical crisis if a patient makes incorrect treatment decisions based on faulty data."

Current standards, which were approved in 2003, require that measurements be within 20 percent—either over or under—of a comparable laboratory test if the blood sugar level is currently above 75 milligrams per deciliter (mg/dL). If blood sugar levels are below 75 mg/dL, the FDA's standard for approval is that the device and strips must be within 15 mg/dL of comparable lab test results, according to Courtney Lias, director of the division of chemistry and toxicology devices at the FDA.

"We weren't really happy with the 20 percent in 2003 but hoped it would improve over time, and we hoped that market pressure would push manufacturers to improve accuracy, but many focused more on adding features," Lias said.

"We've started to talk again about why accuracy standards haven't become better, and now manufacturers are moving toward more accuracy," she said. "Most are moving to meet 15 percent for over 100 mg/dL."

A draft guidance document was released in January by the FDA asking manufacturers to meet the 15 percent goal for 95 percent of blood sugar readings, with the exception of very low blood sugar readings. The guidance document tells manufacturers what the FDA expects of them to gain approval. A draft of the guidance document will be available for several months to allow for public comment before the final document is produced.

However, the accuracy goal refers to numbers achieved prior to device approval. Once the machines and test strips are on the market, Lias

noted, the FDA relies on after-market complaints to the manufacturer, which are supposed to be shared with the FDA, as well as complaints sent directly to the FDA, outreach to the clinical community and FDA inspections.

Some of that feedback to the FDA may be coming from a new campaign, called Strip Safely, started by Bennet Dunlap, a father with two teenagers with type 1 diabetes.

"I was pretty frustrated when I heard that there were blood glucose monitoring systems (devices and test strips) that failed to even meet the 20 percent standard," Dunlap said. In response, he created the Strip Safely campaign to "try to create a call to action for the FDA by the diabetes community."

Dunlap said he wants to be sure that the FDA uses its power to recall faulty diabetes equipment in much the same way that it polices other products.

"The FDA recently recalled cilantro because it contained a risk of 'serious or potentially fatal infections,' according to their press release," he said. "Well, faulty test strips can cause serious and potentially fatal injections [of insulin] in people with diabetes."

The most serious risk from a faulty blood sugar test is that someone with type 1 diabetes (an autoimmune disorder that always requires insulin treatment) or someone with type 2 diabetes who uses insulin could give themselves too little or too much insulin. The most immediate danger would be from too much insulin, which can cause hypoglycemia, or low blood sugar levels. Hypoglycemia causes troubling symptoms, such as shakiness, sweating and confusion, and if left untreated, can cause someone to pass out or even die. Too little insulin results in hyperglycemia, or high blood sugar. Over time, hyperglycemia can lead

to such complications as kidney disease and vision problems.

Dr. David Simmons is chief medical officer of Bayer HealthCare's Diabetes Care, in Tarrytown, N.Y. He said: "People should understand that every time you do a blood sugar test, it's an experiment, and the results have a range. Even tests done in a lab have ranges. Bayer takes accuracy standards very seriously and aimed for a substantial improvement in our new line of meters." He said that 99 to 100 percent of Bayer's new meters meet the 20 percent guideline and about 98 percent meet the 15 percent guideline.

Another manufacturer, Abbott Diabetes Care in Alameda, Calif., "makes substantial investments to monitor and control manufacturing variability," said Jared Watkin, head of technical operations for Abbott. The company has "strict controls in place to ensure consistent quality within each lot and from lot to lot," he said. "Managing diabetes depends on having an accurate understanding of blood glucose levels, so strip accuracy is critical."

Both company spokesmen said they would welcome third party, independent, after-market assessments of their products, which is something that's been proposed to the FDA by the Diabetes Technology Society, a nonprofit organization that focuses on the development and use of technology to fight diabetes.

Watkin said that such assessments could help level the playing field between manufacturers in the United States and those in other countries.

"Research shows that not all strip manufacturers can verify the accuracy of their strips," Watkin said. "Internal tests and third-party published trials show multiple on-market systems fail to meet the [20 percent] performance standards, and there is also evidence of inconsistent adverse event reporting. In addition, foreign-based manufacturers aren't

subjected to unannounced audits by the U.S. FDA."

The FDA's draft guidance document addressed this by asking manufacturers to describe their accuracy on their labels. This would allow consumers to better compare devices and judge for themselves.

Concerns, however, extend beyond manufacturers and standards.

"We are concerned that many Medicare patients have experienced issues getting the strips they want—and those recommended by their doctor—as a result of the competitive bidding program," Watkin said. That program, which started last summer, lowers the cost of blood-testing supplies, but limits where people can go to buy them. "They could unwillingly be getting switched to brands that potentially have lower accuracy," he said.

Dunlap also expressed some worry about people's lack of control over which product they choose and lack of information to make the right choice.

"The expectation that market forces can influence the market depends on a truly free market, and full and complete information," Dunlap said. "Right now, it's difficult to know which devices are more or less accurate."

However, people with diabetes "should continue to test and rely on test strips," the FDA's Lias said. "Be assured that test strips are safe and effective."

And, she said, "if any given test strip result doesn't match the way you feel, retest."

Dunlap urged people to go one step further: If you've had a problem with a blood glucose meter or a test strip, be sure to report it both to the manufacturer and the FDA.

More information: The U.S. Centers for Disease Control and Prevention has more on testing your blood sugar.

For some helpful hints on monitoring your blood sugar, read this *HealthDay* story.

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