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Home Medical Testing Expands, Utility Still Being Explored

► Wendy J. Meyeroff

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Not long ago, the only medical test that patients could use at home was a thermometer. Then in the 1960s, urine tests to measure blood glucose levels became available for home use; in 1976, the first home pregnancy test kit was issued. Today, patients can, among other things, measure their cholesterol, determine a child's paternity, or detect HIV infection.

Steven Gutman, MD, director of the U.S. Food and Drug Administration's (FDA) division of clinical laboratory devices, said that an even broader range of home tests is on the horizon. "Technology is moving like lightning, and a wide range of analytes will give us a dazzling array of products," Gutman promised. "In the last 6 months alone, we've cleared an over-the-counter product to test for fructosamine, designed to be used as an adjunctive test for diabetes, and two manufacturers' home tests for monitoring prothrombin."

The benefit of some home medical tests is not just the test but reporting of the data in a useful format. Plotting the results of tests done regularly at home, such as blood pressure, blood glucose, or peak airflow velocity, "makes the patient's story jump off of the page," said Stephen K. Plume, MD, president of the Hitchcock Clinic in Lebanon, New Hampshire. "We are finding that the patient and physician are becoming much more knowledgeable partners about the disease process. And there are as many stories and learning opportunities as there are patients."

Marilyn Duffy, clinical quality coordinator at Blue Cross/Blue Shield of New Hampshire in Manchester, described the use of peak airflow meters by the health plan's asthmatic patients. One 56-year-old patient had become accustomed to a peak flow of 200 L/min and determined that it was the best she could expect. (The normal range for a woman her age and height is 386 L/min to 418 L/min.) During a triggering episode at Christmas, her airflow reading dropped to 70 L/min and the home monitor indicated that she needed urgent care. She went to the emergency department, received prompt treatment, and returned home feeling better. Since that episode, with twice-daily monitoring that pinpoints environmental triggers, she has worked with her primary care physician to raise her baseline peak flow to 600 L/min.

After years of having patients with diabetes record their blood glucose levels in notebooks that yielded little helpful information, Larry V. Staker, MD, director of clinical practice improvement at Intermountain Health Care in Salt Lake City, developed a specification chart containing a treatment-to-goal line at a glucose level of 110 mg/dL. The chart also contains two other dotted lines, below and above which the patient's measurements should not go. His patients with type 2 diabetes plot their daily fasting plasma glucose level and connect the dots.

"It's magic," described Staker. "Patients immediately see where you want them to be, and they immediately see where they are." It causes them to consider the effects of their activities and become accountable. "This is the first time in 20 years that patients have come to me asking for dietary interventions and changes in medications."

Safety Measures

One of the major concerns physicians express about home tests is whether the patient can perform the test properly without medical supervision and use the results safely and effectively. The FDA will approve a test for home use only if it can be easily used by a consumer, Gutman explained. Instructions are written at a 7th-grade reading level and are accompanied by large, clear illustrations. When the FDA determines that a physician is needed to correctly interpret the results of a home test, as was the case with the two prothrombin tests approved in 1997, the tests are made available by prescription only. This gives the physicians an

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opportunity to provide appropriate training.

Joseph DeVito, MD, clinical instructor of medicine at the New York University School of Medicine in New York City, stated that the type of test is a key determinant of how much education the physician needs to provide. "I think everyone can figure out how to use a home pregnancy test kit." But, he said, there are certain tests, for example the HIV test or the blood pressure cuff, for which the medical provider needs to take some time with the patient. He offered the following example: "When patients are going to be using the blood pressure cuff for the first time, I ask them to bring it in. I test it on myself, to make sure it's giving an accurate reading, then I work with them until I'm satisfied they know how to use it."

Sometimes No Substitute

DeVito added that in some cases the psychological help the physician provides is just as important as clinical expertise. "I'm not sure about HIV home tests. I don't think anything can substitute for pre-and post-test counseling by a professional." Consumers may agree. Home HIV tests have been available for more than a year (Ann Intern Med. 1996;125:1-62-3), but the Confide test by Johnson & Johnson, which received strong marketing support, has been withdrawn from the market because of lack of consumer interest, according to a spokesman. At least three other HIV tests are currently available.

Plume remains optimistic about certain home tests, with a caveat. "We are witnessing the benefits of technologies that are reliable enough so that we don't need to house them in medical facilities, and we're learning, albeit slowly, about the impact of the way the information is presented," he explained. "But it does mean that providers have to let go of some of what they do now."

With home testing, "we're pushing information gathering, reporting, and interpretation into the hands of the people with the problems." Moving these duties out of the sole province of the clinician creates psychological difficulties for both patient and physician that require adequate communication between the two parties, Plume stressed.

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