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PROFESSION

The technology behind the so-called smart pill is slick -- a sensor the size of a grain of sand is added to a medication. When ingested, it sends a signal through the patient's body to a patch worn on the torso, and then transmits that data wirelessly. But the method will succeed in getting patients to take their medications only if they wear the patch. [Photo courtesy of Proteus Digital Health]

Will smart pills, cash boost drug compliance?

Educating patients about taking medications is not always effective. Proponents of technology and incentives say these methods represent the next steps in overcoming a stubborn problem.

By KEVIN B. O'REILLY, amednews staff. *Posted Aug. 20, 2012.*

Innovative technology that can track when a patient ingests a pill is being touted as a way to tackle drug nonadherence. The so-called smart pill joins other new compliance strategies such as financial incentives for patients and game-like applications.

The strategies are the latest methods offered to physicians and others in health care to battle the perennial problem of patients not taking their medicines, which adds billions of dollars to U.S. medical costs annually.

The Food and Drug Administration cleared the smart pill, called the Ingestion Event Marker, for marketing as a medical device on July 10. The ingestible sensor is the size of a grain of sand and can be integrated into an inert pill or an active medication.

Fluid in the stomach activates the sensor and sends a signal through body tissue to a small, water-resistant patch worn on the torso. The patch detects when the pill is ingested and wirelessly sends that data to an application accessible by mobile phone or computer.

Adherence data will be available to anyone given permission by the patient, such as family members and physicians, said the product's manufacturer, Redwood City, Calif.-based Proteus Digital Health Inc. Doctors would have access to their patients' medication-taking patterns between visits and could use it to help address barriers to adherence, said George M. Savage, MD, co-founder and chief medical officer of Proteus.

"This isn't about doctors browbeating people or monitoring compliance in some sort of negative way," Dr. Savage said. "These are tools to help people understand their behavior and to provide directed education and other interventions to help them achieve their goals."

Starting in September, Proteus will partner with the British chain Lloyds Pharmacy to market the product directly to consumers in the United Kingdom. The monthly subscription cost will be on par with the charge for a month of cable or satellite TV service. The sensor will be included in an inert medication to be taken at the same time as the patient's prescribed medications, Dr. Savage said.

Proteus is working with the drugmaker Novartis to add the sensor to immunosuppressive medications prescribed to organ transplant recipients. The company hopes to gain FDA approval for such a "digital medicine" by 2014.

Smart pill has skeptics

Physicians and experts on medication adherence lauded the technological innovation behind the smart pill but said its impact on compliance rates in everyday clinical practice may be limited.

Nonadherence is alarmingly common. Studies have found that a third of new prescriptions never get filled, and patients with chronic conditions are noncompliant with their medications about half the time. About a third of hospital admissions are related to poor drug compliance.

Nonadherence-related ED visits, hospitalizations and doctor visits add at least $100 billion in annual U.S. medical costs, according to the New England Healthcare Institute, a Cambridge, Mass.-based health policy organization. Cost, forgetfulness, medication side effects, lack of motivation and poor understanding of drugs' benefits all contribute to noncompliance, experts say.

Interventional cardiologist Dipti Itchhaporia, MD, often struggles to help her patients stick to their medication regimens that prevent strokes and heart attacks. Having real-time data about patient compliance could be a step forward, yet it is only a first step in the often arduous task of achieving adherence, said Dr. Itchhaporia, chair of the American College of Cardiology's board of governors.

"More information is always helpful, but I think the harder and bigger question is: What do you do when you get that information? It is a free country, after all," said Dr. Itchhaporia, who leads the congestive heart failure management program and the anti-coagulation clinic at Hoag Memorial Hospital Presbyterian in Newport Beach, Calif. "At least it sets the stage for these more important conversations."

Patients who struggle to swallow an old-fashioned pill at the right time may have trouble complying with the Ingestion Event Marker technology, said Hayden B. Bosworth, PhD, a leading expert on drug adherence.

"There are these two parts that need to happen. The patient still needs to wear the patch, so this is not necessarily going to solve the problem," said Bosworth, a professor of psychiatry and behavioral sciences at Duke University School of Medicine in Durham, N.C. "You're not going to convince me that everyone's going to want to walk around wearing patches."

The smart pill may help diagnose nonadherence, but it does little to help solve the causes of the problem, said Walid F. Gellad, MD, MPH, whose research for the RAND Corp. has often focused on noncompliance.

"The issue with adherence is that patients have a lot of barriers to taking their medications," said Dr. Gellad, assistant professor of medicine at the University of Pittsburgh School of Medicine. "And the question is: What barrier is this technology going to address? If cost is the reason patients aren't taking their meds, this device is not going to help at all. In fact, it's going to increase costs."

Taking meds for cash, prizes

The smart pill is not the only innovation being tested to battle nonadherence. Rewarding patients for taking their medicines also is being tested. Giving patients cash or gift cards can have a significant effect on medication adherence, according to a July 16 *American Journal of Medicine* meta-analysis of 21 studies. Incentives studied ranged from as little as $5 per medication visit to as much as $1,000 during a 24-week period. The larger the payment, the greater the effect on adherence rates among patients with conditions such as HIV, tuberculosis and schizophrenia.

The incentives work just as well for affluent patients as they do for low-income patients, said Nancy M. Petry, PhD, the study's lead author and professor of medicine at the University of Connecticut Calhoun Cardiology Center in Farmington, Conn. Some experts, however, wondered whether the incentives would be effective over the long term if the payments are not sustained.

Another strategy to improve medication adherence is to use mobile apps to engage and encourage patients. This method goes beyond cellphone text message reminders to a game-like approach in which patients earn points for activities such as refilling their medications and correctly answering quizzes about their conditions.

One example of this is HealthPrize, which counts two drugmakers and one large pharmacy benefit manager as customers and aims to help patients adhere to medication schedules for conditions such as acne and hypertension. Once patients have earned enough points, they can shop from an online mall for items such as iTunes gift cards and bicycles.

"We have to give people immediate gratification for refilling their medications," said Katrina Firlik, MD, co-founder and chief medical officer of HealthPrize. "No one likes to be a patient with a condition. Too much of health care is not fun. … We make it fun." (**See correction**)

None of these innovations eliminate the need for physicians to talk with their patients about drug compliance, adherence experts said. Doctors should ensure that patients understand why and how to take their medicines, and should keep drug regimens as simple and inexpensive as is medically appropriate. Doctors should ask patients periodically, in a nonjudgmental fashion, about any difficulties they are experiencing in taking their medicines. Physicians should avoid issuing directives and instead use an open-ended conversational approach that prioritizes joint problem-solving, they said.

"This can't be done in isolation," said G. Caleb Alexander, MD, assistant professor in the Dept. of Epidemiology at the Johns Hopkins Bloomberg School of Public Health in Baltimore. "The stronger the physician-patient relationship, the easier these conversations are."

ADDITIONAL INFORMATION:

If drugs were free, would patients take them?

One strategy to improve drug compliance is to remove cost considerations. Researchers randomized nearly 2,900 heart attack patients to one of two groups: One had all drug co-pays covered by an insurer, and the other paid the usual out-of-pocket costs for medications. The intervention improved compliance rates, but not by much.

Medication	Adherence rate with no co-pay	Adherence rate with co-pay
Angiotensin-converting enzyme inhibitor or angiotensin-receptor blocker	41.1%	35.9%
Beta-blocker	49.3%	45.0%
Statin	55.1%	49.0%
All three medications	43.9%	38.9%

Source: "Full Coverage for Preventive Medications after Myocardial Infarction," *The New England Journal of Medicine*, Dec. 1, 2011 (**ncbi.nlm.nih.gov/pubmed/22080794/**)

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"A Networked System for Self-Management of Drug Therapy and Wellness," Proteus Digital Health, October 2010 (**proteusdigitalhealth.com/assets/AuYeung_NetworkedSystemForSelfManagement3.pdf**)

"Financial Reinforcers for Improving Medication Adherence: Findings from a Meta-analysis," *American Journal of Medicine*, published online July 14 (**www.ncbi.nlm.nih.gov/pubmed/22800876/**)

"Medication Non-Adherence: An Ancient Problem In Need of Modern Solutions," HealthPrize Technologies (**www.healthprize.com/content/sites/default/files/HealthPrizeWhitePaper.pdf**)

CardioSmart Med Reminder App, American College of Cardiology (**www.cardiosmart.org/app.aspx**)

"Medication Adherence: Making the Case for Increased Awareness," National Consumers League, May 2011 (**scriptyourfuture.org/wp-content/themes/cons/m/Script_Your_Future_Briefing_Paper.pdf**)

"Full Coverage for Preventive Medications after Myocardial Infarction," *The New England Journal of Medicine*, Dec. 1, 2011 (**www.ncbi.nlm.nih.gov/pubmed/22080794/**)

Correction

This article originally misspelled Dr. Firlik's last name. *American Medical News* regrets the error.

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